

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

L Apr-12-79			79-1	DRS	110128
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SUBMITTED INDIA FOR CL 232,315. ATTACHED: PART X INCLUDES CLINICAL TRIAL PLAN FOR PHASE I AND EARLY PHASE II & PROTOCOL FOR INITIAL PHASE I STUDY TO BE CONDUCTED BY J. DURANT; PART IX INCLUDES CVs FOR DRs. DURANT, GAMS, AND MURRAY. QUALIFICATIONS & PROTOCOLS FOR EACH ADDITIONAL INVEST. WILL BE FILED BEFORE STUDY BEGINS.

F May-21-79				DRS	110127
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ACKNOWLEDGE RECEIPT OF INDIA PERSUANT TO SECTION 505(i) AND ASSIGNMENT OF INDIA NO. 16-332 FOR CL 232,315.

L Jun-01-79			79-2	DRS	110125
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STUDY PROPOSED FOR DR. ARNOLD CANCELLED (ADMINISTR. REASONS) & INITIAL STUDY TO BE PERFORMED BY DR. D. VON HOFF. ITEMS SUBMITTED: V REVISED QC MONOGRAPH OF CL 232,315 PARENTERAL; IX CHECKLIST & CVs FOR VON HOFF & DR. COLTMAN; X REVISED CLINICAL TRIAL PLAN & PROTOCOL FOR VON HOFF'S STUDY.

F Aug-06-79				DRS	110154
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REF. SUBJECT INDIA, RECOMMENDATIONS & REQUESTS: MEDICAL: APPLY RADIONUCLIDE TEST FOR CARDIAC TOX. IN UNIV. OF TEXAS STUDY TO REPLACE CANCELLED STUDY AT UNIV. OF ALABAMA. CHEMISTRY: 19 REQUESTS ON SPECS. AFFECTING CONTROLS & MANUFACTURING. PHARMACOLOGY: REQUEST ANIMAL MODELS DEMONSTRATING COMPARATIVE CARDIOTOX. OF SUBJECT DRUG AND DOXORBUBICIN ETC., ANALAGOUS TO A CLINICAL SITUATION.

F Sep-17-79				DRS	110129
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Led/ Event FLA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		

re. INDA AND AMDT. OF 6/1/79. RECOMMENDATION:
RADIONUCLIDE TECH. FOR CARDIAC TOX. PROPOSED IN
CANCELLED PHASE I STUDY AT UNIV. OF ALABAMA SHOULD
BE APPLIED TO INITIAL PHASE I STUDY AT UNIV. OF
TEXAS.

L Sep-19-79 79-3 DRS 110130

RESP TO FDA LETTER (8/6/79) AND SUPPLYING
QUALIFICATIONS FOR NEW INVEST & PROTOCOL FOR HIS
STUDY. ITEMS ATTACHED: AMEND. A, RESPONSE TO CHEM.
ITEMS 1-9 (IN 8/6 LETT.); PART VI, RESPONSE TO
PHARMACOLOGY REQUEST (IN 8/6 LETT.); PART IX,
CHECKLIST & CVs FOR ALBERTS & HERMAN; PART X,
RESPONSE FOR MURRAY TO MEDICAL RECOMMEND. (IN 8/6
LETT.); PROTO. FOR ALBERTS STUDY TO INCORPORATE
CARDIAC TOX BY RADIONUCLIDE TECH.

L Nov-26-79 79-4 DRS 110131

AMENDED INDA: PART IX, CHECKLIST & CVs FOR
ADDITIONAL INVEST. A. LIPTON & ASSOCIATE DR.
HARVEY; PART X, PROTOCOL FOR LIPTON STUDY -
APPROVED BY CLINICAL INVEST. COMMITTEE. STUDY BY
D. ALBERTS SUSPENDED AT REQUEST OF DR. JOHNSON
(10/15). AFTER DISCUSSED SUPPORTING DATA, JOHNSON
AGREED TO RESUMPTION OF STUDY. E. MCKEON OF LED.
INFORMED AND STUDY NOW IN PROGRESS.

L Dec-04-79 79-5 DRS 110132

re. FDA LETTER 8/6/79 CHEMISTRY (ITEM 1); REQUEST
RELEASE SPECIFICATIONS ON RAW MATERIALS AS
SUPPLIED BY MANUFACT. AND ANY ADDIT. CONTROLS
PERFORMED BY LED. ATTACH. A, (LED. LETTER
9/19/79), INDICATED INFO. TO BE FURNISHED A.S.A.P
(INCLUDED PART V). ITEMS SUBMITTED: PART V,
AVAILABLE MANUFACT. RELEASE SPECS.; PART X,
ADDENDA TO PROTOCOL SUBMITTED 11/2/79 FOR A.
LIPTON STUDY.

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

F Dec-14-79

DRS 110133

REF. INDA AND AMEND. OF 9/19 AND 11/2 AND TELE. CONVERSATION 10/15/79 BETWEEN (LED) MURRAY AND (AGENCY) JOHNSON AND 10/31/79 CONVERSATION BETWEEN (UNIV. ARIZONA) ALBERTS AND JOHNSON. AGREED 10/31, NO OBJECTION TO ALBERTS CONTINUING PHASE I STUDY PROVIDED CLOSE CONTACT WITH VON HOFF IS KEPT REGARDING DEVELOPMENTS IN HIS RELATED STUDY.

L Mar-04-80

80-1 DRS 110134

AMENDED INDA: PART IX, CHECKLIST AND CVs FOR J. HOLCENBERG AND T. VIETTI, AND DRs. FUSNER, LAND & BHANOT; PART X, PROTOCOL FOR HOLLENBERG STUDY, PROTOCOL FOR VIETTI STUDY, & ADDENDA TO PROTOCOL SUBMIT. 9/19/79 FOR ALBERTS STUDY.

L Apr-30-80

80-2 DRS 110135

AMENDED INDA: PART IX, CHECKLIST OF CURRENTLY ACTIVE INVESTIGATORS; PART X, ANNUAL PROGRESS REPORT.

L Jun-20-80

80-3 DRS 110136

AMENDED INDA: PART IX, CVs DRs. WYNERT AND SIMMONDS, ASSOCIATES WITH LIPTON AND STUDY FILED 10/4/79; PART X, CLINICAL REPORT FOR VON HOFF STUDY.

L Aug-19-80

80-4 DRS 110137

AMENDED. INDA PROVIDE FOR PHASE II STUDIES. CLINICAL TRIAL PLAN DESCRIBES ARRANGE. WITH NCI FOR ONCOLOGY GROUP STUDIES. ITEMS INCLUDED: PART VI, ADDITIONAL PRECLINICAL STUDIES; PART VII, UPDATED INVEST BROCHURE; PART IX, UPDATED CV FOR VON HOFF (ORIGINALLY LISTED AS AN INVEST 6/1/79); PART X, CLINICAL TRIAL PLAN, 7 PROTOCOLS FOR PHASE II STUDIES, CLINICAL REPORT FOR ALBERTS STUDY.

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

L Oct-08-80			80-5	DRS		110138
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AMENDED INDIA: PART I, USAN NOMENCLATURE STATEMENT;
PART X, ADDENDUM TO PROTOCOL SUBMIT. 11/2/79 FOR
LIPTON STUDY (EARLIER ADDENDA FILED 12/4/79).
ALSO, TAYLOR PHARMACAL CO., ILL. CONTRACTED TO
MANUFACT. & PACKAGE CL 232,315 FOR LED. EXHIBIT I,
MANUFACT. & CONTROL DOCUMENT. & GMP STATEMENT.
BOTTLES & FINISHED STOCK TO LED. FOR QC RELEASE
TEST PRIOR TO CLINICAL TRIAL.

L Oct-22-80			80-6	DRS		110139
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AMENDED INDIA: PART IX, CVs DRs. BERGAMINI AND
SEDLIS TO ASSIST T. VIETTI; PART X, AMEND. TO
PROTOCOL SUBMIT. 3/4/80 FOR HOLCENBERG STUDY.

L Nov-13-80			80-7	DRS		110140
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AMENDED INDIA: PART IX, UPDATED CV FOR D. ALBERTS &
CVs FOR DRs. WOOLFENDA, PATTON AND AAPRO TO ASSIST
ALBERTS; PART X, PROTOCOL FOR ALBERTS NEW STUDY.
PROTOCOL AMEND. FILED 10/22/80 FOR HOLCENBERG
STUDY ALSO APPLIES TO VIETTI STUDY SUBMIT. 3/4/80.

L Nov-24-80			80-8	DRS		110141
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AMENDED INDIA: PART IX, CHECKLISTS AND CVs FOR 27
ADDITIONAL INVEST., UPDATED CV FOR VON HOFF. ALL
INVESTIGATORS WILL FOLLOW 7 PHASE II PROTOCOLS
SUBMIT. 8/19/80 AND WILL REPORT THROUGH VON HOFF.

L Dec-16-80			80-9	DRS		110142
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AMENDED INDIA: PART X, TWO ADDITIONAL PROTOCOLS FOR
PHASE II STUDIES AND REPORTED THROUGH VON HOFF.
MEMBERS OF GROUP NAMED IN SUBMISSION OF 8/19/80
AND 11/24/80.

led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

L Feb-06-81			81-1	DRS		110143
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AMENDED INDA: PART III, FORMULAS; PART VII, LABELS; PART X, ADDITIONAL PROTOCOL FOR PHASE II STUDIES, AND REPORTED THROUGH VON HOFF. MEMBERS OF GROUP NAMED IN SUBMISSION OF 8/19/80 AND 11/24/80, AMEND. TO PROTOCOL FOR HOLCENBERH & VIETTI SUBMIT. 3/4/80 AND AMENDED 10/22/80.

L Mar-31-81			81-2	DRS		110144
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AMEND INDA: PART III, FORMULA; PART IV, SYNTHESIS RADIOLABELED MITOX.; PART VII, LABELING; PART IX, CHECKLIST SHOWING 3rd STUDY BY ALBERTS (QUALIFICATION SUBMIT 11/13/80), CHECKLISTS 21 ADDIT. INVEST & THEIR CVs, CV FOR DAVIS (ASSOCIATE ALBERTS); PART X, PROTOCOL ALBERTS NEW STUDY, 10 PROTOCOLS FOR PHASE II STUDIES, RESULTS REPORTED THROUGH GAMS, 3 PROTO. FOR PHASE II AND REPORT THROUGH VON HOFF, CLINICAL REPORT FOR LIPTON STUDY.

L Apr-10-81			81-3	DRS		110145
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AMENDED INDA: PART V, ADDIT. STABILITY DATA; PART IX, CHECKLIST FOR ADDITIONAL INVEST. J. ALLEGRA, AND REPORTED THROUGH GAMS, REVISED CHECKLIST NAMING D. WOODWARD MONITOR FOR ALBERTS STUDY SUBMITTED 3/31/81, CV FOR ALLEGRA AND WOODWARD.

L Jun-02-81			81-4	DRS		110146
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AMENDED INDA: PART IX, CHECKLIST OF CURRENT ACTIVE INVEST., CV FOR T. TERZAKIS; PART X, ANNUAL PROGRESS REPORT, AMEND. TO VON HOFF PHASE I STUDY (SUBMIT. 6/1/79), VON HOFF STUDY REPORT.

L Jun-08-81			81-5	DRS		110147
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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

AMENDED INDA: PART IX, CHECKLIST AND CV FOR ADDITIONAL INVEST. J. NEIHART AND CVs FOR ASSOCIATES DRs. MISER AND MALSPEIS; PART X, PROTOCOL FOR NEIDHART STUDY, AMEND. TO HOLCENBERG AND VIETTI STUDIES SUBMIT. 3/4/80 AND AMENDED 10/22/80 AND 2/6/81.

L Jul-08-81 81-6 DRS 110148

AMEND INDA: PART VII, UPDATE BROCHURE FOR INVEST, SAMPLE LETTER WITH ATTACH FROM LEV DESCRIBING INCIDENTS OF CARDIOTOX IN PATS TREATED WITH MITOX. LETTER SENT TO ALL LED INVEST & NCI NOTIFIED BY LEV; PART IX, UPDATED CV VIETTI; PART X, AMEND TO PROTOCOL FOR HOLCENBERG & VIETTI STUDIES SUBMIT 3/4/80 & AMEND 10/22/80, 2/6 & 6/8/81, PROT FOR PHASE II STUDY BY POG, HOLCENBERG & VIETTI COMBINE CLIN REP, ADDENDUM LIPTON REP SUBMIT 3/31/81.

L Jul-31-81 81-7 DRS 110151

AMENDED INDA: PART VI, ADDIT. PRECLINICAL STUDIES; PART VII, SAMPLE LETTER WITH ATTACH. FROM LEV SUMMARIZING 9 CASES OF CARDIOTOX. ASSOCIATED WITH MITOX. & LISTING NEW ENROLL. RESTRICTIONS - SENT TO ALL LED. INVEST.; PART IX, CVs FOR DRs. BERGAMINI, DISTELHORST, LAND, & SEDLIS (ASSOC. TERESA); PART X, REPORT OF AN ADVERSE EXPERIENCE (ONE DESCRIBED IN LEV'S LETTER 7/14/81).

L Sep-08-81 81-8 DRS 110149

AMENDED INDA: PART X, PROTOCOL AMEND. TO ONGOING MITOXANTRONE STUDIES INITIATED BY NCI DUE TO REPORTS OF CARDIOTOX., REPORT OF AN ADVERSE EXPERIENCE.

L Oct-23-81 81-9 DRS 110157

AMENDED INDA: PART X, AMEND. TO PROTOCOL SUBMIT. 3/31/81 FOR ALBERTS STUDY.

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

F Oct-26-81

DRS 110152

REF. INDA: REPORTED 20 CASES CONGESTIVE HEART FAILURES IN PAT. RECEIVING MITOX. REQUIRING A COMPREHENSIVE PLAN FOR FUTURE STUDIES. THIS SUBMISSION SHOULD ACT AS INTERIM PROGRESS REPORT TO INCLUDE TOTAL NO. PAT. ENTERED TO DATE, TUMOR RESPONSE & TYPE OF DOSE SCHED., LIST ALL STUDIES & WHICH STILL OPEN, & INFO. ON TOX. i.e. MOST FREQUENTLY SEEN AND PERCENT OF PAT. OCCUR. REQUEST ALSO BEING MADE OF NCI.

L Nov-30-81

81-10 DRS 110153

RESPONSE TO FDA CORRES. 10/26/81 REGARDING EFFICACY AND SAFETY OF MITOX. ATTACHED REPORT ID'S SOURCES OF DATA AND NO. PATS. INVOLVED. MORE DETAILED REPORT TO BE SUPPLIED BY JANUARY. DRs. ALBERTS AND NEIDHART STUDIES ARE CURRENTLY ACTIVE.

L Dec-30-81

81-11 DRS 110150

AMENDED INDA: PART V, QC MONOGRAPH & RELATED ANALYT. RESEARCH METHOD REPORT 78, UPDATE HPLC ASSAY BULK DRUG SUBSTANCE & PARENT. PREPS.; PART IX, CV & CHECKLIST FOR D. McDONALD, CV FOR R. FOWLER (ASSIST. McDONALD); PART X, PROTOCOL FOR 2 STUDIES BY McDONALD, PROTOCOL FOR PHASE II-III STUDY CONDUCTED BY SWOG & REPORTED THROUGH VON HOFF, AMEND TO PREVIOUS SUBMIT. SWOG PROTOCOLS.

L Mar-04-82

82-1 DRS 110155

AMENDED INDA: PART IX, CHECKLIST AND CV FOR ADDITIONAL INVEST. J. STURGEON; PART X, PROTOCOL AND CRF FOR STURGEON STUDY, REPORT OF ADVERSE EXPERIENCE IN NCI-SPONSORED STUDY.

L Mar-17-82

82-2 DRS 110156

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

AMENDED IND: PART IX, CV M. FUJIMORI TO MONITOR STUDIES PREVIOUSLY ASSIGNED TO MURRAY OR TERZAKIS. WOODWARD & FOWLER CONTINUE TO MONITOR STUDIES INDICATED ON CHECKLIST AT TIME OF PROTOCOL FILING.

L Mar-26-82			82-3	DRS	110158
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REF. FDA CORRES. 10/26/81 AND LED. RESPONSE 11/30/81. REPORT SUMMARIZ. SAFETY & EFFICACY DATA FOR MITOX. SUBMITTED. ITEMS ATTACHED: PART X, MITOX. REPORT, PROPOSED CLIN. OPERATING PLAN, DRUG EXPERIENCE REP. FROM ALBERTS CARDIAC FUNCT. STUDY (LED. SPONSOR), DRUG EXPERIENCE REP. FROM PAT. IN NCI-SPONSORED STUDIES. REQUEST FOR MEETING TO DISCUSS FUTURE CLIN. STUDIES WITH MITOX.

L Apr-20-82			82-4	DRS	110159
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AMENDED IND: PART VI, ADDITIONAL PRECLINICAL STUDIES; PART X, FD FORM 1639 FILED 3/4/82 FOR PAT. B.B., #54585. DISCUSSION OF CARDIAC DIFFICULTIES AND 'NOT CONTRIBUTING TO DEATH'. AFTER FURTHER REVIEW, RELATIONSHIP WOULD BE CLASSIFIED AS 'POSSIBLE'. (SEE LETTER FOR MORE DETAILED DESCRIPTION OF CARDIAC DIFFICULTIES.)

L May-06-82			82-5	DRS	110126
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AMENDED IND SUBMIT.: IX, CHECKLIST OF CURRENTLY ACTIVE INVEST.; X, ANNUAL PROGRESS REPORT.

L May-25-82			82-6	DRS	111759
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IN ANTICIPATION OF 6/23/82 MEETING, SUBMIT 1)PROSPECTIVE CLINICAL OPERATING PLAN, 2)PROTOCOL FOR STUDY IN PATIENTS WITH BREAST CANCER.

L Jun-07-82			82-7	DRS	110351
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Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

AMEND. SUBJECT INDA: PART VII, REVISED BROCHURE FOR INVEST.; PART IX, CHECKLIST STUDY BY YAP (BODEY CO-INVEST.), CVS YAP & BODEY AND ASSOC. BLUMENSCHIN, EWER, BENJAMIN, HORTOBAGYI, SCHELL, AND WALLACE; PART X, PROTOCOL FOR YAP AND BODEY STUDY.

L Jun-11-82 82-8 DRS 110515

AMEND SUBJECT INDA: PART IX, CHECKLIST & CV FOR ROWAN & ASSISTANTS TONG & BLOCK; PART X, PROTOCOL FOR CHLEBOWSKI'S STUDY.

L Jun-14-82 82-9 DRS 110514

PURSUANT TO TELE. CONVERSATION WITH JOHNSON(FDA) 6/9/82, SENDING ADDITIONAL PROTOCOLS FOR REVIEW PRIOR TO MEETING 6/23. CALL ATTENTION TO PROTOCOL SUBMIT 6/7/82 FOR YAP & BODEY STUDY (ITEM 5 ON TABLE 1 OF PROSPECTIVE CLIN. OPERATING PLAN).

L Jul-13-82 82-10 DRS 110832

AMEND SUBJECT INDA: PART VII, PHARMACY BROCHURE; PART IX, CHECKLIST & CVS FOR SILVER LEVICK GRACE ALLEGRA WOODCOCK & WOLFF, CV FOR ASSISTS PASMANTIER COLEMAN NACHMAN JAROWSKI SOLF RUGGIERO RESNICK CHIARIERI SALETAN MOLANDER(SILVER), LEVICK DESAI(LEVICK), JOHNSTON SARG(GRACE), KUBOTA RICHMAN BLUMENREICH(ALLEGRA), & GRECO HAINSWORTH BRENNER HANDE(WOLFF); PART X, PROT & CRF FOR MULTI-CENTER STUDY, DRUG EXPERI FROM NCI STUDY.

L Jul-15-82 82-11 DRS 110827

SUBMIT TO SUBJECT INDA PACKAGE 2 DRUG EXPERIENCE REPORTS FROM NCI STUDIES OMITTED FROM 7/13/82 SUBMIT.

L Jul-22-82 82-12 DRS 111760

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		

AMEND SUBJECT INDA: PART IX, CHECKLIST & CV FOR 5 NEW INVESTIGATORS & CVs FOR THEIR ASSOCIATES (REF HARD COPY LETTER FOR LIST OF NAMES); PART X, DRUG EXPERIENCE REPORT. FIVE NEW INVEST TO FOLLOW PROTOCOL SUBMIT 7/13/82.

L Jul-29-82 82-13 DRS 111062

AMEND SUBJECT INDA: CHECKLIST & CVs FOR SPICER, PERLOFF & DUGAN, CVs FOR MITCHELL, ARDALAN, BERTRAM, GRUNBERG, KEMPF, & DANIELS (ASSIST SPICER), CVs FOR ELLISON, HYMAN, OSTER, STOOPLER, & RAPOPORT (ASSIST PERLOFF), CVs FOR SCHROEDER, BATES, & WORKMAN (ASSIST DUGAN); PART X, EXPLAIN CARDIOTOX MONITOR FOR SURGEON STUDY (SUBMIT 3/4/82). 3 INVEST ABOVE TO FOLLOW PROT SUBMIT 7/13/82.

L Aug-05-82 82-14 DRS 111092

AMEND SUBJECT INDA: PART IX, CHECKLIST & CV FOR ROSS, CV FOR KRAMER (ASSIST ROSS). ROSS TO FOLLOW PROTOCOL SUBMIT 7/13/82.

L Aug-18-82 82-15 DRS 111185

AMEND SUBJECT INDA: PART IX, CHECKLIST & CVs FOR MOORE, DAO & VOLBERDING, CVs FOR NEMOTO & PATEL (ASSIST DAO), CV FOR GENTILE (ASSIST ALLEGRA & WOODCOCK IN STUDY SUBMIT 7/13/82); PART X, AMEND TO PROTOCOL TO AFFECT DAO'S STUDY ONLY. ALL INVEST TO FOLLOW PROTOCOL SUBMIT 7/13/82.

L Aug-24-82 82-16 DRS 111222

AMEND SUBJECT INDA: PART IX, CHECKLIST & UPDATED CV FOR NEIDHART & CVs FOR ASSOC BALCERZAK, BOURONCLE, DEWALD, GREVER, KRAUT, METZ, RINEHART, ROACH, SOGONE, WALL, & WILSON; PART X, PROT FOR NEIDHART STUDY & SAMPLE COMPUTER CRF. SPONSOR FOR 1st NEIDHART STUDY (ON SINCE 11/80) TRANSFER FROM NCI TO LED. DETERMIN OF PHARMACOKINETIC PARAMETER DELETED FROM PROT OBJECTIVE. UPDATED TOX STUDIES INCLUDED.

Led/ Event FCA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		

L Sep-03-82			82-17	DRS	111245
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AMEND SUBJECT INDA: PART IX, CHECKLIST & CVs FOR DOTY & GOLOMB, CVs FOR KANE & REGAN (ASSIST DOTY), CVs FOR ALBAIN, BARON, GAYNOR, HOFFMAN, LARSON, NEELY, PEARSON, ULTMANN, VAN SHEPARD, & WADE (ASSIST GOLOMB). DOTY & GOLOMB TO FOLLOW PROTOCOL SUBMIT 7/13/82.

L Sep-10-82			82-18	DRS	111250
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AMEND SUBJECT INDA: PART IX, CHECKLIST FOR SILVER 2nd STUDY (QUALIF SUBMIT 7/13/82), CHECKLIST & CVs FOR ARMENTROUT, BROWN, & GOLDMAN, CVs FOR BROWER & MOORE (ASSIST SILVER), STATER (ASSIST ARMENTROUT), GALLAGHER, JOIST, D.LUEDKE, S.LUEDKE, & PETRUSKA (ASSIST BROWN), GRADY, BURNINGHAM, GALEN (ASSIST GOLDMAN); PART X, PROT TO BE FOLLOWED BY SILVER, ARMENTROUT & BROWN. GOLDMAN TO FOLLOW PROT SUBMIT 7/13/82.

L Sep-17-82			82-19	DRS	111277
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AMEND SUBJECT INDA: PART IX, CHECKLIST FOR COSTANZI 2nd STUDY, CHECKLIST & CV FOR ERSLEV, UPDATED CV FOR COSTANZI, CHECKLIST FOR BLOCK (QUALIF FILED 6/11/82), CVs FOR ALPERIN GARDNER, GUPTA, & WEISS (ASSIST COSTANZI), CVs FOR 10 ERSLEV'S ASSOCIATES (SEE HARD COPY FOR NAMES). BLOCK TO FOLLOW PROT SUBMIT 7/13/82. COSTANZI & ERSLEV FOLLOW PROT SUBMIT 9/10/82.

L Sep-29-82			82-20	DRS	111320
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REF SUBJECT INDA; SUBMIT NOTED FROM 6/23/82 MEETING WITH FDA.

L Oct-01-82			82-21	DRS	111323
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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

AMEND SUBJECT INDA: PART IX, CHECKLIST & CV FOR ARLIN & CVs FOR ASSIST CLARKSON, GEE, KEMPKIN, MERTELSMANN, & STRAUS. ARLIN TO FOLLOW PROTOCOL SUBMIT 9/10/82.

L Oct-07-82 82-22 DRS 111347

AMEND SUBJECT INDA: PART IX, CHECKLIST & CVs FOR WHITE, BITRAN, & AMARE, CVs FOR BILLINGS, DESSER, KOSLOFF, NEWMAN, ROBIN, SHAPIRO, & SWEET (ASSIST BITRAN), CVs FOR BODENSTEINER, COOK, LYNCH, & SKIKNE (ASSIST AMARE); PART X, AMEND TO PROT FOLLOWED BY SILVER, ALLEGRA, WOODCOCK, & PERLOFF. WHITE & BRITTAN TO FOLLOW PROT SUBMIT 7/13/82, AMAR FOLLOW PROT SUBMIT 9/10/82.

L Oct-18-82 82-23 DRS 111358

AMEND SUBJECT INDA: PART IX, CHECKLIST & CVs FOR STARLING, MISER, MULNE, & MILLER, CV FOR FERNBACH, MAHONEY & STEUBER (ASSIST STARLING), CV FOR NEWTON, ROACH & RUYMANN (ASSIST MISER & MULNE), CV FOR HOFFMAN & TAN (ASSIST MILLER); PROTOCOL & CRF FOR MULTICENTER STUDY.

L Oct-25-82 82-24 DRS 111368

AMEND SUBJECT INDA: PART IX, CHECKLIST FOR ADDITIONAL STUDY BY GAMS, CHECKLIST & CV FOR CASSELETH AND VATS, CV FOR THUEWORTHY (ASSIST VATS), UPDATED CV FOR GAMS. GAMS & CASSELETH TO FOLLOW PROTOCOL SUBMIT 9/10/82. VATS TO FOLLOW PROTOCOL SUBMIT 10/18/82.

L Nov-08-82 82-25 DRS 111402

AMEND SUBJECT INDA: PART IX, CHECKLIST FOR 2nd MOORE STUDY (QUALIF SUBMIT 9/18/82); PART X, AMEND TO NEIDHART PROTOCOL SUBMIT 8/24/82, DER FOR BOTH LED AND NCI SPONSORED STUDIES. MOORE TO FOLLOW PROTOCOL SUBMIT 9/10/82.

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Dec-03-82			82-26	DRS	111461
		AMEND SUBJECT INDA: PART IX, CV FOR BERNHARDT (ASSIST SILVER); PART X, ADDENDUM TO PROTOCOL SUBMITTED 7/13/82.			
L Dec-08-82			82-27	DRS	111465
		AMEND SUBJECT INDA: PART IX, CHECKLIST & CVS FOR PETERSON & STEIN, CVS FOR BARNES, BLOOMFIELD, HRUSHESKY, HURD, KENNEDY, KENYON, AND KIANG (PETERSON ASSOC); PART X, PROTOCOL TO BE FOLLOWED BY PETERSON & STEIN.			
L Dec-13-82			82-28	DRS	111445
		AMEND SUBJECT INDA: PART IX, CV FOR DUKART TO REPLACE FUIJIMORI AS LED MONITOR; PART X, AMEND TO PROTOCOL SUBMITTED 6/7/82.			
F Dec-29-82		TELEPHONE CALL		DRS	830034
		DR.JOHNSON TO DR.B.J.CLARK (CONFM 1/10/83)			
		(a) PROTOCOL Questioned 1st line therapy for non-Hodgkins lymph			
L Jan-04-83		AMENDMENT	83-1	DRS	830163
		(a) CV,CKLST PT9 /003-046-006 DP3-46 SUBM 12/8/82, AMENDED 6/21/83 GAMS,RICHARD A LYMPHOMA NON-HODGKIN'S			
		AMEND SUBJECT INDA: PART IX, CHECKLIST & UPDATED CV FOR GAMS. GAMS TO FOLLOW PROTOCOL SUBMITTED 12/8/82.			
L Jan-10-83	F Dec-29-82	AMENDMENT	83-2	DRS	830021
		RIVKIN STUDIES			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

- (a) CV & CKLST
 PT9 /003-046-001
 Updated
 RIVKIN, SAUL E
 LYMPHOMA
 NON-HODGKIN'S
- (b) CV
 PT9 /003-046-001
 Assoc:Drs.Godman,Kaplan,Wasserman,Weber
- (c) PROTOCOL
 PT10 /003-046-001
 Amend re eligibility,radiotherapy,wbc before next
 RX course
- (d) PROTOCOL # /PT 10 F
 Hold admit pts w/non-Hodgkins lymphoma until appr

AMEND SUBJECT INDA: PART IX, CHECKLIST AND UPDATED
 CV FOR RIVKIN & CV FOR ASSOCIATE GOODMAN, KAPLAN,
 WASSERMA, & WEBER; PART X, AMEND TP PROT SUBMIT
 7/13/82. RIVKIN TO FOLLOW PROTOCOL SUBMIT 10/8/82.

1 Jan-25-83

AMENDMENT 83-3 DRS 830071
 COSTANZI/GOLOMB/JONES/CASE/SCHWARTZ/STUART STUDIES

- (a) CV(& ASSOCs),CKLST
 PT9c,f /003-044-011
 DP3-44 SUBM 9/10/82
 SCHWARTZ,I ROBERT
 LEUKEMIA
- (b) CV(& ASSOCs),CKLST
 PT9c,g /003-046-005
 DP3-46 SUBM 12/8/82
- (c) CV,CKLST
 PT9c /003-046-009
 DP3-46 SUBM 12/8/82
- (d) CKLST
 PT9a /003-046-008
 DP3-46 SUBM 12/8/82; COSTANZI'S CV (& ASSOCs) SUBM
 9/17/82
 COSTANZI,JOHN J
 LYMPHOMA
 NON-HODGKIN'S
- (e) CKLST,CV-ASSOC(s)
 PT9b,d /003-046-003
 DP3-46 SUBM 12/8/82; JONES' CV SUBM 11/24/80

Led/ Event FCA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		<p>JONES,STEPHEN E LYMPHOMA NON-HODGKIN'S (f) CKLST,CV-ASSOC(s) PT9b,e /003-046-007 DP3-46 SUBM 12/8/82; GOLOMB'S CV SUBM 9/3/82 GOLOMB,HARVEY M LYMPHOMA NON-HODGKIN'S</p> <p>AMEND SUBJECT INDA: PART IX, CHECKLIST FOR COSTANZI, JONES, & GOLOMB NEW STUDIES, CHECKLIST & CVs FOR SCHWARTZ, STUART, & CASE, CVs FOR JONES, GOLOMB, SCHWARTZ, & STUART'S ASSOCIATES (REF HARD COPY LETTER FOR NAMES).</p>			
L Jan-31-83	L Sep-10-82	AMENDMENT ADDITIONAL INVESTIGATOR	83-4	DRS	830105
		<p>(a) CV,CKLST PT9 /003-044-012 DP3-44 SUBM 9/10/82 SARTIANO,GEORGE P LEUKEMIA</p> <p>(b) CV # /PT 9 Assoc:Drs.Babcock,Butler,Gonzalez,McFarland</p> <p>(c) CV # /PT 9 Assoc:Drs.Puckett,Smith,Valdivieso</p> <p>AMEND SUBJECT INDA: PART IX, CHECKLIST AND CV FOR SARTIANO, CVs FOR ASSOCIATES BABCOCK, BUTLER, GONZALEZ, McFARLAND, PUCKETT, SMITH, & VALDIVIESO. SARTIANO TO FOLLOW PROTOCOL SUBMIT 9/10/82.</p>			
L Feb-03-83		AMENDMENT SILVER M.C. NON-HODGKINS LYMPHOMA;M.C. ADULT ACUTE LEUKEMIA	83-5	DRS	830132
		<p>(a) CKLST,CV-ASSOC(s) PT9 /003-046-010 DP3-46 SUBM 12/8/82, AMND' 6/21/83; SILVER'S CV SUBM 7/13/82 SILVER,RICHARD T LYMPHOMA NON-HODGKIN'S</p>			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		

- (b) PROTOCOL
PT10 /003-046-010
No patients on 1st line therapy
- (c) PROTOCOL # /PT 10
DP 3-44 dosage amended,originally submitted
9/10/82

AMEND SUBJECT INDIA: PART IX, CHECKLIST FOR SILVER
THIRD STUDY, CV FOR 2 ADDITIONAL ASSOCIATES MOORE
AND WOLF; PART X, AMEND TO PROT SUBMIT 9/10/82.
SILVER TO FOLLOW PROT SUBMIT 10/8/82.

F Feb-04-83

DRS 830135
6/7/82 MESTASTIC BREAST CA;12/8/82 NON-HODGKINS
LYMPH SUBMIS

- (a) PROTOCOL
Exclude Novantrone as single agent w/non-Hodg lymf
- (b) INVEST BROCH
2/82,pg116:clar elig,monit prior heart
dis,cardiomyopathy

REF APPLICATION FOR INDIA & LED CORRES 6/7 &
12/8/82. APPROVE INITIATION OF CLIN TRIALS. HAVE
FOLLOWING RECOMMENDATIONS: (1)IN PROT SUBMIT
12/8/82, SHOULD MODIFY TO EXCLUDE AS FIRST LINE
THERAPY, PAT WITH NON-HODGKINS LYMPHOMA, AND
(2)CLINICAL BROCHURE SHOULD STATE ELIGIBILITY
RESTRICTIONS REGARDING PRIOR HEART DISEASE.

I Feb-09-83

AMENDMENT 83-6 DRS 830130
SARTIANO/BODEY STUDIES

- (a) CV(& ASSOCs),CKLST,PROT
PT9,10 /003-047-001
BODEY,GERALD P
- (c) CKLST,CV-ASSOC(s) /003-040-0
PROT SUBM 7/13/82
SARTIANO,GEORGE P
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS

AMEND SUBJECT INDIA: PART IX, CHECKLIST FOR 2ND
SARTIANO STUDY, CHECKLIST FOR NEW BODEY STUDY.
UPDATED CV FOR BABCOCK (ASSOCIATE OF SRATIANO),
CVs FOR BURGESS, ESTEY, LEGHA, & VALDIVIESO
(ASSIST BODEY); PART X, PROTOCOL FOR BODEY STUDY.
SARTIANO TO FOLLOW PROTOCOL SUBMIT 7/13/82 AND
AMENDED 1/10/83.

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		

L Feb-14-83

AMENDMENT 83-7 DRS 830124
KREMENTZ/VOGEL/HOLLAND/PLOTKIN/MUGGIA STUDIES

- (a) CKLST & PROTOCOL
PT9,10 /003-048-004
KREMENTZ, EDWARD T
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
- (b) CV, CKLST, PROTOCOL
PT9,10 /003-055-001
HOLLAND, JAMES F
ALL
COMBINED w/ VINCRISTINE & DEXAMETHASONE
- (c) CV, CKLST, PROTOCOL
PT9,10 /003-048-001
MUGGIA, FRANCO
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
- (d) CV, CKLST, PROTOCOL
PT9,10 /003-048-005
PLOTKIN, DAVID
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
- (e) CV, CKLST, PROTOCOL
PT9,10 /003-048-002
VOGEL, CHARLES L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
- (f) CV # /PT 9
Assoc: Dr. Wang
- (g) CV # /PT 9
Assoc: Drs. Cuttner, Harris, Ohnuma, Paciucci
- (h) CV # /PT 9
Assoc: Drs. Carter, Sutherland
- (i) CV # /PT 9
Assoc: Drs. Blum, Bottino, Green, Levin, Speyer, Spiegel, Wernz

AMEND SUBJECT INDA: PART IX, CHECKLIST FOR
DREMENTZ SECOND STUDY, CHECKLIST & CVs FOR BOGEL,
HOLLAND, PLOTKIN, AND MUGGIA, UPDATED CV FOR
CARTER & SUTHERLAND, CVs FOR VOGEL, HOLLAND &
MUGGIA ASSOCIATES (SEE HARD COPY FOR NAMES); PART
X, PROT FOR VOGEL, KREMENTZ, PLOTKIN, & MUGGIA
STUDIES, PROT FOR HOLLAND STUDY.

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Feb-24-83			83-8	DRS	111629
		AMEND SUBJECT INDIA: PART IX, CHECKLIST AND CVs FOR BYRNE & JUSS, CV FOR WOOLLEY (ASSIST BYRNE), CVs FOR PASCHOLD, CAPONERA & POPE (ASSIST MUSS), CV FOR BRAICH (ASSIST JONES IN STUDY SUBMIT 1/25/83). BYRNE & MUSS TO FOLLOW PROTOCOL SUBMIT 2/14/83.			
L Mar-02-83			83-9	DRS	111663
		AMEND SUBJECT INDIA: PART IX, CHECKLIST & CV FOR DESAI, CV FOR DIMITROV TO ASSIST NEIDHART. DESAI WILL FOLLOW PROTOCOL SUBMIT 2/14/83. MULNE WILL BE ASSUMING RESPONSIBILITY FOR PROTOCOL STUDY SUBMIT 10/18/82 FOR MISER.			
L Mar-04-83			83-10	DRS	111664
		AMEND SUBJECT INDIA: PART IX, CVs FOR BODEY'S ASSISTANTS ON STUDY PROTOCOL SUBMIT 2/9/83 (REF HARD COPY LETTER FOR NAMES).			
L Mar-07-83			83-11	DRS	111666
		AMEND SUBJECT INDIA: PART IX, CHECKLIST & CVs FOR DECONTI & BRODOVSKY, CVs FOR BYRNE, DAVIS, FLATOW, HETZEL, ROSS, STEINGART, & WHITE (ASSIST DECONTI), CVs FOR LAUCIUS & HOLROYDE (ASSIST BRODOVSKY). DECONTI & BRODOVSKY TO FOLLOW PROTOCOL SUBMIT 2/14/83.			
L Mar-17-83			83-12	DRS	111690
		AMEND SUBJECT INDIA: PART IX, CHECKLIST FOR 3rd GOLOMB STUDY, CHECKLIST & CV FOR PAPISH & ASSOCIATES KRITZMAN, MIER, MILLER, PARKINSON, RUDDERS, & TAYLOR, CV FOR LESTER & VOGELZANG (ASSIST GOLOMB). GOLOMB & PAPISH TO FOLLOW PROTOCOL SUBMIT 2/14/83. ACKNOWL RECEIPT FDA 2/4/83 LETTER AND IMPLEMENTING RECOMMENDATIONS MADE.			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
L Mar-22-83			83-13	DRS		111701
		AMEND SUBJECT INDIA: PART IX, CHECKLIST SHOWING NEW STUDY FOR GAMS & CV FOR ASSOCIATES PERLMAN AND KARDINAL. GAMS TO FOLLOW PROTOCOL SUBMIT 2/14/83.				
L Mar-31-83			83-14	DRS		111715
		AMEND SUBJECT INDIA: PART IX, CHECKLIST & CVs FOR BENNETT & DOROSHOW, CV FOR BAKEMEIER, CARIGNAN, & MCCUNE (ASSIST BENNETT), CV FOR BERTRAND, BROWNING, CARR, & OVERBY (ASSIST DOROSHOW), CHECKLIST SHOWING ADDRESS CHANGE FOR ARLIN, UPDATED CV FOR ARLIN. BENNETT & DOROSHOW TO FOLLOW PROTOCOL SUBMIT 2/14/83.				
L Apr-06-83			83-15	DRS		111750
		AMEND SUBJECT ANDA: PART IX, CHECKLIST FOR HOLLAND 2ND STUDY; PART X, PROTOCOL FOR HOLLAND NEW STUDY.				
L Apr-22-83		AMENDMENT	83-16	DRS		830226
		PROTOCOL SUPPLEMENT TO GAM'S STUDY IN ADULT LEUKEMIA				
		AMEND SUBJECT INDIA: PART X, PROTOCOL SUPPLEMENT TO GAM STUDY SUBMIT 9/10/82.				
L May-11-83		AMENDMENT	83-17	DRS		830285
		SCHEIN ASSISTING BYRNE IN STUDY FILED 2/24/83				
		AMEND SUBJECT INDIA: PART IX, CV FOR SCHEIN TO ASSIST BYRNE IN STUDY FILED 2/24/83.				
L May-27-83		AMENDMENT	83-18	DRS		830343
		BERTINO/BENNETT STUDIES				
L Jun-13-83		AMENDMENT	83-19	DRS		830382

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(a) PROG RPT & CKLST # /PT 9,10			
L Jun-15-83		AMENDMENT MULTICTR NON-HODGKIN'S LYMPH STUDY	83-20	DRS	830433
		(a) CKLST # /PT 9 ERSLEV, ALLAN J			
L Jun-21-83		AMENDMENT AMEND TO MULTICTR NON-HODGKIN'S LYMPHOMA PROTO SUB 12/8/82	83-21	DRS	830483
L Jun-24-83		AMENDMENT	83-22	DRS	830496
L Jun-29-83		AMENDMENT HENDERSON STUDY	83-23	DRS	830502
L Jul-06-83		AMENDMENT	83-24	DRS	830560
		(a) DRUG EXPER RPT # /PT 10 NCI-Sponsored Study			
L Jul-25-83		AMENDMENT	83-25	DRS	830628
		(a) CV, CKLST # /PT 9 MULTI-CENTER BREAST CANCER PROTOCOL SUBMT'D 2/14/83 MORGAN, LEE ROY CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
L Jul-29-83		AMENDMENT CV'S VARIOUS ASSTS; HOLLAND STUDY	83-26	DRS	830635
		(a) PROTOCOL PT 9, 10 /003-065-001 HOLLAND, JAMES F LYMPHOMA COMBINED w/ VINCRISTINE & DEXAMETHASONE			
L Aug-08-83		AMENDMENT	83-27	DRS	830645

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(a) CV & PROTOCOL # /PT 9 PROTOCOL SUBM 7/29/83 HOLLAND, JAMES F			
		(b) CV & PROTOCOL # /PT 9 7/29/83 SUBM CORRECTION: CV SUBM 3/31/83; STUDYING AC LEUKEM			
1 Aug-09-83		AMENDMENT	83-28	DRS	830646
		(a) CV # /PT 9 DR GAMS' ASSISTANTS IN BREAST CA STUDY			
		(b) INVEST SITE ADDITIONAL SITE FOR AC MYELOBLASTIC LEUKEMIA STUDY WIERNIK, PETER H LEUKEMIA			
1 Aug-12-83		AMENDMENT	83-29	DRS	830654
		MULTICENTER BREAST CA STUDY			
		(a) CV # /PT 9 ASS'T TO DR J. EVERETT			
1 Aug-17-83		AMENDMENT	83-30	DRS	830663
		(a) CKLST /003-048-0 REPLACES DECONTI; PROT 3-48 SUBM 2/14/83; CV SUBM 3/7/83 WHITE, CHARLES F CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		(b) PROTOCOL EMERGENCY TREATMENT BESIDES FORMAL STUDY			
		(d) CV-ASSOC(s) /003-048-0 test ??? MUST WE HAVE INDIVIDUAL RR6-RR7 RECORDS FOR EACH??			
1 Aug-26-83		AMENDMENT	83-31	DRS	830688
		(a) PROTOCOL # /PT 10 AMEND TO AC MYELOBL LEUK PROT SUBMD 4/6/83			
		(b) PROTOCOL AMEND TO REFRACTORY LYMPHOMA STUDY SUBMITTED 7/29/83			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Aug-30-83		AMENDMENT	83-32	DRS	830692
		(a) CV(& ASSOCs),CKLST PT9 /003-040-025 PROT SUBM 7/13/82, AMENDED 1/10/83 BERNARD,STEPHEN A CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
L Sep-07-83		AMENDMENT	83-33	DRS	830705
		(a) FORMULA # /PT 3 (b) MONOGRAPH # /PT 5 CONTROLS (c) STABILITY # /PT 5 (d) LABEL # /PT 7 (d) LABEL # /PT 7 (e) CV # /PT 9 ASSISTANTS TO DRS R GAMS, E KREMENTZ			
L Sep-12-83		AMENDMENT		DRS	830732
		(a) CV CV'S FOR DR DENNETT'S ACCOCIATES			
L Sep-14-83		CORRESPONDENCE REQUEST 1-A IND/NDA CLASSIFICATION		DRS	830736
		(a) SUMMARY NOTES FROM 5/3/83 LED-FDA MTG: MTX'S ADVNTGS OVER EXIST THER (b) SUMMARY DR CLARK PROFILE OF MTX: SAF/EFFIC IN TREATING ADV BREAST CA			
L Oct-06-83		AMENDMENT	83-36	DRS	830785
		(a) CV # /PT 9 CV FOR DR BODEY'S NEW ASST -FORMER COINVSCTR,DR YAP, LEAVES			
L Oct-10-83		AMENDMENT	83-37	DRS	830787
		(a) CV,CKLST CV'S FOR DR ARLIN & ASSOC'S. ADD'L ASSOC CV SUBM 3/31/83			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		ARLIN,ZALMEN A CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
L Oct-20-83		AMENDMENT PART 10-AMNDMT TO PHASE I-II PROT (DP 3-55) SUBM 2/14/83	83-38	DRS	830815
L Oct-25-83		AMENDMENT ADD'L PRE-CLINICAL STUDIES, PART 6	83-39	DRS	830828
L Oct-28-83		AMENDMENT (a) CV,CKLST # /PT 9 CKLST FOR DR ELLISON (CV SUBM 10/6/83) & CV'S FOR HER ASSOCS (b) CV # /PT 9 DR TESTER (DR LEVICK'S ASSOC); DR GREENBERG (BLOCK'S ASSOC) (c) SUMMARY # /PT 9 DR ELLISON REPLACES DR PERLOFF (LEFT) AS PRINC INVSCTR	83-40	DRS	830840
L Oct-31-83		CORRESPONDENCE REQUEST COMMENTS ON PROSPECTIVE PROTOCOLS(2) & CLIN STRATEGY	83-41	DRS	830843
L Nov-02-83		AMENDMENT (a) CV,CKLST,PROTOCOL PT9 /003-000-000 WEINER,MARTIN J	83-42	DRS	830853
L Nov-09-83		AMENDMENT (a) PROTOCOL # /PT 10 REVISIONS (SECTNS 4.25 & 6.52) TO DR BODEY'S PROT SUB 6/7/82	83-43	DRS	830867
L Nov-11-83		AMENDMENT (a) CKLST,CV-ASSOC(s) PT9a /003-048-009 DP 3-48 SUBM 2/14/83, AMND' 2/28/84; CV SUBM 3/17/83	83-44	DRS	830875

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		PARKINSON, DAVID R CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU (c) PROTOCOL /003-044-0 BERTINO'S CV AND CKLST SUBM 5/27/83; ONE PT-COMPASSION BASIS BERTINO, JOSEPH LEUKEMIA				
L Nov-30-83		AMENDMENT	83-45	DRS		830903
		(a) CKLST PT9a /003-048-017 PROT SUBM 2/14/83; CV's SUBM 7/13/82 WOLFF, STEVEN N CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU (b) CV # /PT 9b CV's FOR 3 ASSOC'S OF DR R GAMS (#34) UNDER PROT SUB 2/14/83				
L Dec-02-83		AMENDMENT	83-46	DRS		830912
		(a) CV, CKLST, PROTOCOL PT9,10 /003-070-000 CV FOR DR JONES. HIS 3 ASSOCS' CV's WERE FILED 2/14/83 JONES, ROY CA-BREAST; DOSE RANGING ESCALATING DOSE -CARDIAC MEASUREMENTS				
L Dec-12-83		CORRESPONDENCE UPDATED CARDIOTOX RPT TO SUPPORT REQUEST FOR 1A IND/NDA CLAS	83-47	DRS		830930
L Dec-13-83		AMENDMENT	83-48	DRS		830932
		(a) CKLST, PROT PT9a,10 /003-072-001 CV SUBM 7/22/82 HENDERSON, I CRAIG CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION				

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOKANTRONE CL 232,315 ANTICANCER AGENT			
		(b) CV,CKLST,INVEST AGREE # /PT 9b DR ARLIN(#85) TO FOLLOW THE MULTI-CTR BR CA PROT SUB 2/14/83			
L Dec-19-83		AMENDMENT	83-49	DRS	830943
		(a) CKLST # /PT 9 CL FOR DR QAZI(CV FILED 7/29/83);SUBBING FOR DR BENNETT,#111			
L Jan-04-84		AMENDMENT	84-1	DRS	831034
		(a) CV # /PT 9 CVs FOR 2 ASSOCS OF DR BERTINO (#113) FOR PROT SUBM 11/11/83			
L Jan-20-84		AMENDMENT	84-2	DRS	831068
		(a) INVEST BROCH # /PT 7 ADDENDUM TO 6/7/82 BROCHURE; RE: CARDIOTOXICITY			
		(b) CV(& ASSOCS),CKLST PT9 /003-048-019 PROTO SUBM 2/14/83 GEORGE,SEBASTIAN CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
F Jan-23-84		CORRESPONDENCE REQUEST INFO ON POSSIBLE CAUSES & REMEDIES OF PRECIPITAION		GRP	831073
L Jan-31-84	B Dec-21-83	CORRESPONDENCE SUMMARY/NOTES OF PRE-NDA DISCUSSION --FOR FDA REVIEW	84-3	DRS	831095
L Feb-01-84		AMENDMENT	84-4	DRS	831106
		(a) CKLST /003-048-0 PROT SUBM 2/14/83; CV(& ASSOCS) SUBM 8/30/83 BERNARD,STEPHEN A CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT			
L Feb-14-84		AMENDMENT	84-5	DRS		831144
		(a) CV,CKLST,INVEST AGREE # /PT 9a DR WEIDEN(#124) WILL FOLLOW MULTI-CTR BR CA PROT SUB 2/14/83				
L Feb-21-84		AMENDMENT	84-6	DRS		831156
		(a) CKLST,PROT PT9a,10 /003-071-001 CV SUBM 1/25/83 CASE,DELVYN C LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(b) CKLST,PROT PT9a,10 /003-074-001 CV SUBM 1/25/83 CASE,DELVYN C ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
L Feb-22-84		AMENDMENT	84-7	DRS		831160
		(a) DEAR INVESTIGATOR LETTER # /PT 7 WARNING TO READ LABELS CAREFULLY; OD(DEATHS) AT FOREIGN HOSP				
		(b) DEAR PHARMACIST LETTER # /PT 7 WARNING TO READ LABELS CAREFULLY; OD(DEATHS) AT FOREIGN HOSP				
		(c) CV,CKLST,PROTO PT9,10 /003-075-001 UPDATED CV ALBERTS,DAVID S CA-OV,COLON; DOSE RANGING PK OF IP ADMINISTRATION				
F Feb-23-84	L Feb-23-84	ADVERTISING		ECM		831163
		TORONTO TELECONFERENCE SEEN AS PROMOTION OF UNAPPROVED DRUG				
L Feb-28-84		AMENDMENT	84-8	DRS		831166
		(a) CV,CKLST,INVEST AGREE # /PT 9a,c DR CONRAD(#125) WILL FOLLOW MULT-CTR BR CA PROT SUBM 2/14/83				

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(b) CV,CKLST,INVEST AGREE # /PT 9b,c DR CHLEBOWSKI(#60;2nd STUDY) TO FOLL ADV BR CA PROT 12/13/83			
		(c) PROTOCOL AMNDMT TO MULTI-CTR CR CA PROT SUBM 2/14/83			
L Mar-05-84		AMENDMENT	84-9	DRS	831266
		(a) CKLST PT9a /003-071-003 PROT SUBM 2/21/84; CV SUBM 10/10/83 ARLIN,ZALMEN A LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(b) CKLST PT9a /003-074-002 PROT SUBM 2/21/84; CV SUBM 10/10/83 ARLIN,ZALMEN A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Mar-20-84		AMENDMENT	84-10	DRS	831289
		(a) CV,CKLST PT9a /003-071-002 DP 3-71 SUBM 2/21/84 MABRY,R JAMES LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(b) CV,CKLST PT9a /003-071-004 DP 3-71 SUBM 2/21/84 COHEN,RICHARD J LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
L Mar-21-84		AMENDMENT	84-11	DRS	831290
		(a) CV # /PT 9 CV's FOR DRs ALVAREZ & RODRIGUES, DR ARLIN'S(#85) ASSISTANTS			
L Mar-27-84		AMENDMENT	84-12	DRS	831300
		(a) CV,CKLST PT9a /003-048-024 DP 3-48 SUBM 2/14/83, AMENDED 2/28/84			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		PRESANT,CARY A CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU (b) CV,CKLST PT9b /003-048-023 DP 3-48 SUBM 2/14/83, AMENDED 2/28/84 TRUMP,DONALD L CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU (c) CV,CKLST PT9b /003-048-025 DP 3-48 SUBM 2/14/83, AMENDED 2/28/84 DENEFRIO,JOHN M CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
L Mar-30-84		AMENDMENT	84-13	DRS	831302
		(a) CKLST PT9a /003-071-008 DP 3-71 SUBM 2/21/84; CV SUBM 1/25/83			
		(b) CV,CKLST PT9b /003-071-005 DP 3-71 SUBM 2/21/84 DRESDNER,DAVID M LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(c) CV,CKLST PT9b /003-071-007 DP 3-71 SUBM 2/21/84 BLUMING,AVRUM Z LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(d) CV,CKLST /003-074-0 DP 3-74 SUBM 2/21/84 DRESDNER,DAVID M ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Mar-30-84	F Jan-23-84	CORRESPONDENCE BUFFERED BISULFITE-FREE FORMULA^N HAS REPLACED FORMER FORM^N	84-14	GRP	831310

Led/ Event FIA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
L Apr-02-84		AMENDMENT	84-15	DRS		831334
		(a) CKLST PT9a /003-071-006 MUL-CTR COMB REGIMEN PROT SUBM 2/21/84; CV SUBM 7/13/82 WOODCOCK, THOMAS M LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
L Apr-09-84		AMENDMENT	84-16	DRS		831347
		(a) CKLST, CV-ASSOC(s) PT9a /003-048-026 PROT SUBM 2/14/83, AMENDED 2/28/84; CV SUBM 7/13/82 GRACE, WILLIAM R CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU				
		(b) PROTOCOL # /PT 10 AMNDMT TO HEPATOMA PROT SUBM 6/11/82 (DR R CHLEBOWSKI #60)				
F Apr-11-84	L Sep-14-83	NOT APPROVABLE REQUEST FOR 1A CLASSIFICATION DENIED		DRS		831351
L Apr-16-84		AMENDMENT	84-17	DRS		831360
		(a) CV, CKLST PT9abc /003-071-012 DP 3-71 SUBM 2/21/84 ABBRUZZESE, JAMES L LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(b) CV, CKLST PT9abc /003-071-009 DP 3-71 SUBM 2/21/84 GOODMAN, GARY E LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(c) CV, CKLST PT9abc /003-071-013 DP 3-71 SUBM 2/21/84				

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		HOLROYDE, CRISTPHER P LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(d) CKLST PT9abc /003-071-010 DP 3-71 SUBM 2/21/84; STEIN'S (2nd STUDY) CV SUBM 12/8/82 STEIN, RICHARD S LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(e) CKLST PT9abc /003-071-011 DP 3-71 SUBM 2/21/84; CV SUBM 7/13/82 WOLFF, STEVEN N LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
L Apr-19-84		AMENDMENT	84-18	DRS		831369
		(a) CKLST PT9a /003-072-003 3-72 SUBM 12/13/83; CV SUBM 7/13/82 WOODCOCK, THOMAS M CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION				
L Apr-23-84		AMENDMENT	84-19	DRS		831370
		(a) CV CVs FOR 3 ASSTs OF DR D SPICER (#71)				
L Apr-30-84		AMENDMENT	84-20	DRS		831379
		(a) CKLST PT9a /003-071-014 PROT SUBM 2/21/84; CV(& ASSOCs) SUBM 3/31/84 BENNETT, J/QAZI, RAMAN LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(b) CV(& ASSOCs), CKLST PT9b /003-074-004 PROT SUBM 2/21/84 GROPPE, CARL W ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
		(c) CV-ASSOC(s) PT9c /003-071-014 BERMAN, LEVINE, STREETER, RASSIGA				

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16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT			
L May-02-84		AMENDMENT	84-21	DRS		831408
		(a) CKLST PT9 /003-071-016 PROT SUBM 2/21/84; CV SUBM 2/28/84 CONRAD, MARCEL E LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
L May-04-84		AMENDMENT	84-22	DRS		831415
		DR KRAKOFF REPLACES DR BODEY(#100) AS PRINCIPLE INVESTIGATOR				
		(a) CV,CKLST PT9 /003-041-001 KRAKOFF REPL BODEY AS PRIN INV; DP3-41 SUBM 6/7/82 KRAKOFF, I H CA-BREAST COMB w/ CYCLOPHOS, 5-FU X-OVER TO ADRIAMYCIN/VINBLASTINE				
		(b) CV(& ASSOCS),CKLST PT9 /003-071-015 DP3-71 SUBM 2/21/84 SHAW, JOHN LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(c) CV,CKLST PT9 /003-047-001 KRAKOFF REPL BODEY AS PRIN INV; DP3-47 SUBM 2/9/83 KRAKOFF, I H				
		(d) INVESTIGATOR REPLACEMENT /003-041-0 BODEY REPLACED BY KRAKOFF BODEY, GERALD P CA-BREAST COMB w/ CYCLOPHOS, 5-FU X-OVER TO ADRIAMYCIN/VINBLASTINE				
		(e) INVESTIGATOR REPLACEMENT /003-047-0 BODEY REPLACED BY KRAKOFF BODEY, GERALD P				
L May-22-84		AMENDMENT	84-23	DRS		831449
		(a) CV(& ASSOCS),CKLST PT9a,d /003-048-027 DP3-48 SUBM 2/14/83, AMND 2/28/84; UPDATED CV				

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		OISHI, NOBORU CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		(b) CKLST PT9b,c /003-071-018 DP3-71 SUBM 2/21/84; CV(& ASSOCS) SUBM 9/3/82 DOTY, GORDON L LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(c) CV, CKLST PT9b,c /003-071-017 DP3-71 SUBM 2/21/84; ASSOCS' CVs SUBM 3/27/84 KENNEDY, PETER S LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(d) CV(& ASSOCS), CKLST PT9b,c /003-071-019 DP3-71 SUBM 2/21/84 GABRIEL, DON A LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(e) CV(& ASSOCS), CKLST PT9b,c /003-071-012 DP3-71 SUBM 2/21/84 LEVINE, JAMES D LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(f) CV(& ASSOCS), CKLST PT9b,c /003-071-020 DP3-71 SUBM 2/21/84 SCOTT, ROBERT B LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(g) INVESTIGATOR REPLACEMENT /003-071-0 ABBRUZZESE REPLACED BY LEVINE ABBRUZZESE, JAMES L LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
L May-23-84		AMENDMENT	84-24	DRS	831463
		(a) CV, CKLST PT9a /003-000-000 DP3-48 SUBM 2/14/83, AMND 2/28/84; ONE PT, COMPASSIONATE, OL			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		SAMUELS, ARTHUR J (b) CV, CKLST PT9a /003-048-028 PROT SUBM 2/21/84 BENIGNO, BENEDICT R CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU (c) CV(& ASSOCs), CKLST PT9a /003-071-021 DP3-71 SUBM 2/21/84 FASS, LEROY LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
L May-30-84		AMENDMENT	84-25	DRS		831481
		(a) CV, CKLST PT9 /003-074-005 MULTICTR COMBO REGIMEN ACUTE NONLYMPH LEUK PROT SUBM 2/21/84 TRANUM, BILL L ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
L May-31-84		AMENDMENT	84-26	DRS		831480
		(a) CKLST # /PT 9 CURRENTLY ACTIVE INVESTIGATORS (b) PROGRESS RPT # /PT 10 ALBERTS, DAVID S CA-OV, COLON; DOSE RANGING PK OF IP ADMINISTRATION ARLIN, ZALMEN A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) ARLIN, ZALMEN A LYMPHOMA; vs m-BACOD m-BNCOD COMBO BERNARD, STEPHEN A CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU BERNARD, STEPHEN A CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS				

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16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		

BERTINO,JOSEPH
LEUKEMIA

CASE,DELVYN C
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
CASE,DELVYN C
LYMPHOMA

NON-HODGKIN'S
CASE,DELVYN C
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

DENEFRIO,JOHN M
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

DENEFRIO,JOHN M
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

GAMS,RICHARD A
LYMPHOMA
NON-HODGKIN'S
GOLOMB,HARVEY M
LYMPHOMA

NON-HODGKIN'S
GRACE,WILLIAM R
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

GRACE,WILLIAM R
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS

HENDERSON,I CRAIG
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION

HOLLAND,JAMES
HOLLAND,JAMES F

ALL
COMBINED w/ VINCRISTINE & DEXAMETHASONE
HOLLAND,JAMES F
LYMPHOMA

COMBINED w/ VINCRISTINE & DEXAMETHASONE
JONES,ROY
CA-BREAST; DOSE RANGING
ESCALATING DOSE -CARDIAC MEASUREMENTS

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16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		

JONES,STEPHEN E
LYMPHOMA
NON-HODGKIN'S
KRAKOFF,IH /BODEY
KREMENTZ,EDWARD T
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
MORGAN,LEE ROY
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
MUGGIA,FRANCO
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PARKINSON,DAVID R
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PLOTKIN,DAVID
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PRESANT,CARY A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
RIVKIN,SAUL E
LYMPHOMA
NON-HODGKIN'S
SCHWARTZ,I ROBERT
LEUKEMIA

SEBASTIAN,GEORGE
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
SILVER,RICHARD T
LYMPHOMA
NON-HODGKIN'S
STUART,JOHN J
LYMPHOMA
NON-HODGKIN'S
TRUMP,DONALD L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

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16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		
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VOGEL, CHARLES L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WHITE, CHARLES F
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WOLFF, STEVEN N
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WOODCOCK, THOMAS M
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION
WOODCOCK, THOMAS M
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION

L Jun-06-84

AMENDMENT	84-27	DRS	831531
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- (a) CKLST
PT9acd /003-071-023
DP3-71 SUBM 2/21/84; CV SUBM 10/7/82
BITRAN, JACOB
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
- (b) CKLST
PT9acd /003-071-025
DP3-71 SUBM 2/21/84; CV SUBM 9/10/82
BROUN, GORONWY O
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
- (c) CV, CKLST
PT9acd /003-071-024
DP3-71 SUBM 2/21/84
STONE, LAWRENCE A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
- (d) CV, CKLST
PT9acd /003-071-022
DP3-71 SUBM 2/21/84
VOYCE, GARY F
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
- (e) CV, CKLST, PROTO, INVES AGR
PT9b /003-074-006
ADDL STUDY BY DR GAMS; CV SUBM
1/4/83; PROT(3-74) SUBM 2/21/84

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT			
L Jun-14-84		AMENDMENT IN REFERENCE TO DR NEIDHART'S(#56) BREAST CA STUDY (3-43-1)	84-28	DJF		831543
		(a) CASE REPORT FORM GLOSSARY OF ABBREV'NS/CODES(FOR CRFs) PREPARED BY DSU CA CTR				
L Jun-15-84		AMENDMENT	84-29	DRS		831545
		(a) CKLST PT9a /003-071-014 CV SUBM 7/29/83; DP3-71 SUBM 2/21/84; QAZI CO-INV W/ BENNETT QAZI, RAMAN LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
L Jun-19-84		AMENDMENT	84-30	DRS		831561
		(a) CKLST PT9acd /003-071-028 DP3-71 SUBM 2/21/84; CV(& ASSOCS) SUBM 1/4/83,6/6/84 GAMS,RICHARD A LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(b) CKLST PT9acd /003-071-029 DP3-71 SUBM 2/21/84; CV(& ASSOCS) SUBM 6/24/83 WIERNIK,PETER H LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(c) CV(& ASSOCS),CKLST PT9acd /003-071-026 (3-71) SUBM 2/21/84 HEIM,WILLIAM J LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(d) CV,CKLST PT9acd /003-071-027 (3-71) SUBM 2/21/84 WACHI,DENNIS H LYMPHOMA; vs m-BACOD m-BNCOD COMBO				

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(e) CKLST PT9acd /003-072-004 DP3-72 SUBM 12/13/83; CV(& ASSOCS) SUBM 10/10/83 ARLIN,ZALMEN A CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION			
		(f) CV(& ASSOCS),CKLST PT9acd /003-074-007 DP3-74 SUBM 2/21/84 ABRAMSON,NEIL ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(g) CV,CKLST PT9acd /003-074-006 DP3-74 SUBM 2/21/84 VILLA,LUIS ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(h) CKLST PT9acd /003-074-008 DP3-74 SUBM 2/21/84; CV(&ASSOCs) SUBM 6/24/83 WIERNIK,PETER H ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Jun-22-84		AMENDMENT	84-31	DRS	831566
		(a) CV,CKLST PT9a /003-074-009 DP3-74 SUBM 2/21/84 HICKS,WILLIAM J ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Jul-02-84		AMENDMENT	84-32	DRS	831667
		(a) CKLST PT9a /003-071-030 PROT 3-71 SUBM 2/21/84; CV(& ASSOCS) SUBM 7/13/82, 2/3/83 SILVER,RICHARD T LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(b) CV,CKLST PT9b /003-043-001 ROACH REPL NEIDHART(#56) AS PRIN INV IN DP 3-43 SUBM 8/24/82			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		(c) ROACH,RALPH W PROTOCOL /003-000-0 QAZI FOLLOWING (BUT NOT PART OF) DP3-48 SUBM 2/14/83 QAZI,RAMAN				
I Jul-12-84		AMENDMENT	84-33	DRS		831691
		(a) CKLST PT9a /003-071-031 PROT 3-71 SUBM 2/21/84; CV SUBM 3/7/83 WHITE,CHARLES F LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(b) CKLST PT9b /003-040-009 HESKETH REPL LOPEZ AS PRN INV; DP3-40 SUB 7/13/82;CV-4/30/84 HESKETH,PAUL /LOPEZ CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS				
		(c) CV,CKLST PT9b /003-048-029 PROT 3-48 SUBM 2/14/83, AMENDED 2/28/84 PORTLOCK,CAROL S CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU				
I Jul-13-84		AMENDMENT	84-34	DRS		831692
		(a) CV # /PT 9 CVs FOR 3 ASSTs UNDER DR GRACE (#63; 3-40-3 -SUBM 7/13/82)				
I Jul-20-84		AMENDMENT	84-35	DRS		831702
		(a) CV # /PT 9 CVs FOR 5 ASSTs TO TRUMP(#128;3-48-23); 3-48 SUBM 2/14/83				
L Jul-23-84		AMENDMENT	84-36	DJF		831711
		DER FROM DR DAO'S TRIAL (3-40-16) -MULTI-CTR BR CA PROT 3-40				
		(a) DRUG EXPER RPT # /PT 10 PT #3018 (AGE:30yrs) AMENORRHEA, HOT FLASHES				

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT			
L Jul-26-84		AMENDMENT	84-37	DJF		831705
		(a) CKLST PT9a /003-071-033 PROT 3-71 SUBM 2/21/84; ARMENTROUT'S CV SUBM 9/10/82 ARMENTROUT, STEVEN LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(b) CV,CKLST PT9a /003-071-032 PROT 3-71 SUBM 2/21/84; JAFFREY, IRA S LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
		(c) CV-ASSOC(s) PT9c /003-071-028 11 ASSOCS TO GAMS (PROT SUBM 2/21/84)				
L Jul-27-84	L Jul-13-84	CORRESPONDENCE		DJF		831742
		7/13/84 COVER LTR SHOULD HAVE READ 16,332 & NOT 17,560				
L Jul-30-84		AMENDMENT	84-38	DJF		831740
		(a) CV,CKLST PT9 /003-074-010 DP3-74 SUBM 2/21/84 WEINTRAUB, LEWIS R ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
L Aug-06-84		AMENDMENT	84-39	DJF		831756
		(a) CKLST PT9a /003-074-012 DP3-74 SUBM 2/21/84; CV(& ASSOCS) SUBM 9/3/82 DOTY, GORDON L ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
		(b) CV,CKLST PT9b /003-071-034 DP3-71 SUBM 2/21/84 DOSIK, MICHAEL H LYMPHOMA; vs m-BACOD m-BNCOD COMBO				

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Aug-07-84		AMENDMENT	84-40	DJF	831763
		(a) CKLST PT9a /003-071-023 DESSER (CV-10/7/82) REPLACES BITRAN AS PR INV FOR 3-71-23 BITRAN, JACOB LYMPHOMA; vs m-BACOD m-BNCOD COMBO DESSER, R K /BITRAN LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(b) CV-ASSOC(s) # /PT 9b 4 ASSOCS OF DR H GOLOMB FOR 2 BR CA STUDIES -3-40-21, 3-48-21			
L Aug-14-84		AMENDMENT	84-41	DJF	831774
		(a) CV, CKLST, PROTO PT9, 10 /003-069-001 UPDATED CV MOORE, JOSEPH O CA-LUNG WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA			
L Aug-15-84		MEETING	84-42	DJF	831777
		REQUEST MTG SEPT 24-26: ACUTE LEUKEMIA & NON-HODGKIN'S LYMPH			
L Aug-16-84		AMENDMENT	84-43	DJF	831812
		(a) CKLST PT9a /003-074-011 3-74 SUBM 2/21/84; CV(& 13 ASSOCS) SUBM 1/4/83, 6/6, 7/26/84 GAMS, RICHARD A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(b) CV-ASSOC(s) PT9b /003-048-008 FOR 2 ASSTs TO DR BRODOVSKY (#109 -3/7/83) IN STUDY 3-48-8			
		(c) CV-ASSOC(s) PT9b /003-048-007 1 ASST TO DR HOLROYDE (#134 -4/16/84) IN STUDY 3-71-13			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		(d) CV-ASSOC(s) PT9c	/003-048-007			
		(d) CV-ASSOC(s) PT9c	/003-071-031			
		(e) CV-ASSOC(s) PT9d FOR 8 ASSTs	/003-048-023			
L Aug-23-84		AMENDMENT	84-44	DJF		831825
		(a) DEAR INVESTIGATOR LETTER # /PT 7 TO ALL ACTIVE INVS: AMENORRHEA IN PTS BEING TREATED W/ MITOX				
L Aug-24-84		AMENDMENT	84-45	DJF		831829
		(a) ALL INVSTGTRS (EXCEPT HEIM) WILL FOLLOW 3-74 SUBM 2/21/84				
		(b) CKLST PT9b DP3-74 SUBM 2/21/84; CV(& ASSOCS) SUBM 5/22/84,8/30/83 GABRIEL,DON A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)	/003-074-016			
		(c) CKLST PT9a DP3-74 SUBM 2/21/84; CV(& ASSOCS) SUBM 7/13/82,2/3/83 SILVER,RICHARD T ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)	/003-074-017			
		(d) CV(& ASSOCS),CKLST PT9c DP3-74 SUBM 2/21/84 DOSIK,HARVEY ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)	/003-074-015			
		(e) CV(& ASSOCS),CKLST PT9c DP3-74 SUBM 2/21/84 KLOSS,ROBERT A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)	/003-074-014			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(f) CV(& ASSOCs),CKLST PT9c /003-074-013 DP3-74 SUBM 2/21/84 ROBINSON,WILLIAM ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(g) CV-ASSOC(s) PT9d /003-071-026 FOR 1 ASST TO DR HEIM (#150 -6/19/84) IN STUDY 3-71-26			
L Aug-30-84		AMENDMENT	84-46	DJF	831835
		(a) CV-ASSOC(s) # /PT 9 1 ASST TO DR WHITE(#116 -8/17/83); PROT 3-48 SUBM 2/14/83			
		(b) DRUG EXPER RPT # /PT 10 STUDY 3-48-8 (PT: EP #4102): HYPOTENSION			
L Sep-05-84		AMENDMENT	84-47	DJF	831852
		(a) CV(& ASSOCs),CKLST PT9a /003-074-018 DP3-74 SUBM 2/21/84; CV FOR 4 ASSOCs SCHADE,STANLEY G ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(b) CV-ASSOC(s) # /PT 9b 1 ASST TO TRUMP(#128,3-48-23,3/27/84); DP3-48 SUBM 2/14/83			
L Sep-06-84		AMENDMENT	84-48	DJF	831853
		(a) CKLST PT9a /003-069-002 DP 3-69 SUBM 8/14/84; CV(& ASSOCs) SUBM 5/22/84 & 8/30/83 BERNARD,STEPHEN A CA-LUNG WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA			
		(b) CV-ASSOC(s) PT9b /003-071-014 BRENNAN,OLSON,ROWE			
		(c) CV-ASSOC(s) PT9c /003-074-007 JADEJA,MAHAJAN			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Sep-12-84		AMENDMENT	84-49	DJF	831861
		(a) CV(& ASSOCs),CKLST PT9 /003-074-019 DP3-74 SUBM 2/21/84 KARP,DANIEL D ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Sep-19-84		AMENDMENT	84-51	DJF	831878
		(a) CKLST PT9a /003-071-035 (3-71-35); CV(& ASSOC) SUBM 1/20/84; DP3-71 SUBM 2/21/84 GEORGE,SEBASTIAN LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(b) CV-ASSOC(s) # /PT 9b 2 ASSOCs OF DR BITRAN(#87,3-40-23-10/7/82);3-40 SUBM 7/13/82			
		(c) CV-ASSOC(s) # /PT 9c 7 ASSOCs OF PORTLOCK(#156,3-48-29-7/12/84);3-48 SUBM 2/14/83			
		(d) DRUG EXPER RPT # /PT 10 PT#1006,3-74-2: DEATH -3hrs AFTER MITO + Ara-C ADMINISTERED			
L Sep-20-84		AMENDMENT	84-52	DJF	831881
		(a) CV-ASSOC(s) # /PT 9 4 ASSOCs TO TRUMP(#128,3-48-23 3/27/84); DP3-48 SUBM 2/14/83			
L Sep-26-84		AMENDMENT	84-53	DJF	850125
		(a) CKLST,CV-ASSOC(s) PT9a,b /003-040-021 REPL GOLOMB(#79) AS PR INV IN 3-40 SUBM 7/13/82,AMND 1/10/83 BITRAN,JACOB /GOLOMB CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS GOLOMB,HARVEY M CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

- (b) CKLST, CV-ASSOC(s)
PT9a,b /003-048-010
BITRAN REPL GOLOMB AS PR INV IN 3-48 SUBM 2/14/83,
A 2/28/84
BITRAN, JACOB /GOLOMB
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
BITRAN, JACOB /GOLOMB
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
GOLOMB, HARVEY M
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
- (c) CV-ASSOC(s)
PT9b /003-046-007
3-46 SUBM 12/8/82, AMND 6/21/83; BITRAN'S CV SUBM
10/7/82
- (d) CV-ASSOC(s)
PT9c /003-071-034
FOR 12 ASSTs TO DR M DOSIK(#159-8/16/84); 3-71
SUBM 2/21/84
- (e) PROTOCOL AMENDMENT
PT10a /003-065-000
A#2 -PROT ORIG SUBM 7/29/83, AMND 8/26/83
- (f) PROTOCOL AMENDMENT
PT10b /003-074-000
A#1 -PROT SUBM 2/21/84

L Oct-04-84		AMENDMENT	84-54	DJF	831938
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- (a) CV(& ASSOCs), CKLST
PT9a /003-074-020
3-74 SUBM 2/21/84, AMENDED 9/26/84
WEAVER, ZEBULON III
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

L Oct-17-84		AMENDMENT	84-55	DJF	831935
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- (a) CV-ASSOC(s)
PT9 /003-071-001
1 ASST TO CASE (#98,3-71-1 SUBM 2/21/84)

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16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT			
L Oct-19-84		AMENDMENT	84-56	DJF		831939
		(a) CV-ASSOC(s) # /PT 9 4 ASSTS TO ARLIN (#85,3-44-13,10/1/82); 3-44 SUBM 9/10/82				
L Oct-24-84		AMENDMENT	84-58	DJF		831942
		(a) CKLST & PROTOCOL PT9 /003-074-021 CV SUBM 9/10/82 ARMENTROUT,STEVEN ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
L Oct-24-84		CORRESPONDENCE	84-57	DJF		831941
		COPY OF 9/26 MINUTES: EVAL'N OF MITO IN PTS W/ LEUK/LYMPHOMA				
L Oct-29-84		AMENDMENT	84-59	DJF		831962
		(a) CKLST & PROTOCOL PT9,10 /003-000-000 CV SUBM 12/3/82 BERNHARDT,BERNARD				
L Nov-05-84		AMENDMENT	84-60	DJF		832033
		(a) CV-ASSOC(s) PT9 /003-046-002 7 ASSTS TO PETERSON (#94-12/8/82); PROT SUBM 12/8/82				
L Nov-07-84		AMENDMENT	84-61	DJF		832036
		(a) CV-ASSOC(s) PT9a /003-071-013 2 ASSTS TO HOLROYDE(#134-4/16/84); DP3-71 SUBM 2/21/84				
		(b) CV-ASSOC(s) PT9b /003-000-000 PHILLIPS ASST'g BERNHARDT IN PROT SUBM 10/29/84,1PT-COMPASSN				

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
L Nov-09-84	L Oct-24-84	CORRESPONDENCE	84-62	DJF		832038
		(a) PUBLISHED RPTS SWOG PAPER (CANCER '79): ADRIAMYCIN'S CONTRIBUTION DIFF LYMPH				
L Nov-13-84		AMENDMENT	84-63	DJF		832040
		(a) CKLST PT9 /003-069-003 DP3-69 SUBM 8/14/84; CV(& ASSOCs) SUBM 4/9/84,7/13/82 SARG, MICHAEL J CA-LUNG WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA				
L Nov-14-84		AMENDMENT	84-64	DJF		832042
		(a) CV-ASSOC(s) PT9a /003-048-020 ASST TO BERNARD(#117-2/1/84); DP3-48 SUBM 2/14/83,A-2/28/84				
		(b) CV-ASSOC(s) PT9b /003-074-015 2 ASSTs TO DOSIK(#163-8/24/84); DP3-74 SUBM 2/21/84,A9/26/84				
L Nov-27-84		AMENDMENT	84-65	DJF		832067
		(a) PROTOCOL AMENDMENT PT10 /003-046-000 AMNDMT 2 (DP3-46 ORIG SUBM 12/8/82, FIRST AMND' 6/21/83)				
L Nov-30-84		AMENDMENT	84-67	DJF		832069
		(a) CV,CKLST PT9 /003-000-000 SPAULDING FOLLOWING (BUT NOT PART OF) DP3-40 SUBM 7/13/82 SPAULDING, MONICA B				
L Dec-05-84		AMENDMENT	84-68	DJF		832103
		(a) CV-ASSOC(s) PT9 /003-071-031 ASST TO WHITE (#116,7/12/84); DP3-71 SUBM 2/21/84				

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT			
L Dec-20-84		AMENDMENT IN SUPPORT OF PRESERV EFFICACY -VIALS AS MULT-DOSE CONTAINER	84-69	GRP	F	832144
		(a) PRESERVATIVE EFFICACY # /PT 5 AT 30 MINS; 1,7,14,21,28 DAYS (EXHIBIT #1)				
		(b) PRESERVATIVE EFFICACY # /PT 5 AT 6,24,48 HRS & 7,14,21,28 DAYS (EXHIBIT #2)				
		(c) ANALYSES # /PT 5 MULT-USE EVAL'N: REPEATED EXTRACTIONS FROM A SINGLE VIAL 30d				
		(d) MONOGRAPH # 15530 /PT 5 GENERAL MTD: ANTIMICROBIAL PRESERVATIVES EFFECTIVENESS				
L Jan-02-85		AMENDMENT	85-1	DJF		832126
		(a) DRUG EXPER RPT PT10 /003-074-007 PT#2019 DEATH: FIBRILLATION ATRIAL				
L Jan-18-85		AMENDMENT	85-2	DJF		850033
		(a) CKLST, PROT PT9a,10a /003-076-001 CV SUBM 10/4/84 WEAVER,ZEBULON III CA-SOLID; COMPASSIONATE				
		(b) CV,CKLST,PROTO PT9b,10b /003-077-001 COOPER,MILES R LEUKEMIA; COMPASSIONATE				
F Jan-22-85	L Oct-24-84	CORRESPONDENCE IF MITO ADDS TO RESULTS OF H-D CYTARAB (ANLL) EFFICACY SHOWN		DJF		850274
		(a) EFFICACY(NOD LYMPH): IMPROVE QUALITY OF LIFE;SURVIV DATA REQ				
L Feb-19-85		AMENDMENT	85-3	DJF		850120

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(a) CKLST PT9a /003-000-000 DP3-65 SUBM 7/29/83, AMENDED 8/26/83,9/26/84. CV SUB 2/14/83 HOLLAND,JAMES			
		(b) CV,CKLST PT9b /003-076-002 DP3-76 SUBM 1/18/85 GRILLO,JAMES CA-SOLID; COMPASSIONATE			
		(c) PROTOCOL AMENDMENT PT10 /003-075-001 A#1: PTS OVER 70yrs WILL BE ADMITTED; DP3-75 SUBM 2/22/84			
L Feb-26-85		AMENDMENT	85-4	DJF	850142
		(a) CV-ASSOC(s) PT9 /003-071-015 ASST TO SHAW (#138 -5/4/84); DP3-71 SUBM 2/21/84			
		(b) DRUG EXPERIENCE RPT # /PT 10 (U.K. STUDY 3-563-1, PT# 1/G.N.) INTESTINAL PERFORATION			
L Mar-01-85		AMENDMENT	85-6	DJF	850189
		(a) CV,CKLST PT9a /003-076-003 PROT SUBM 1/18/85 LOWENBRAUN,STANLEY CA-SOLID; COMPASSIONATE			
		(b) CV(& ASSOCs),CKLST PT9b /003-076-004 PROT SUBM 1/18/85 SCHER,NANCY CA-SOLID; COMPASSIONATE			
		(c) CKLST PT10c /003-076-005 PROT SUBM 1/18/85; CV SUBM 7/26/84 UNDER PROT 3-71-32 JAFFREY,IRA S CA-SOLID; COMPASSIONATE			

led/ Event FCA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		(d) CKLST PT10d /003-076-006 PROT SUBM 1/18/85; CV SUBM 3/27/84 UNDER PROT 3-48-5 DENEFRIO, JOHN M CA-SOLID; COMPASSIONATE				
		(e) /003-076-0 DR Z WEAVER(#166) WILL BE TREATING AN ADDL PATIENT				
		(f) /003-077-0 DR COOPER(#170) WILL BE TREATING AN ADDL PATIENT				
L Mar-08-85		AMENDMENT	85-8	DJF		850179
		(a) DRUG EXPERIENCE RPT # /PT 10 (CANADA) EXTRAVASATION; SWELLING, BLISTERING, WEAKNESS -HAND				
L Mar-15-85		AMENDMENT	85-8	DJF		850214
		(a) CV(& ASSOCs),CKLST PT9 /003-077-002 PROT SUBM 1/18/85 McFARLAND, JAMES A LEUKEMIA; COMPASSIONATE				
L Mar-25-85		AMENDMENT	85-9	DJF		850239
		(a) CV(& ASSOCs),CKLST PT9a /003-076-007 PROT SUBM 1/18/85 HORVATH, WILLIAM L CA-SOLID; COMPASSIONATE				
		(b) CV-ASSOC(s) PT9b /003-074-015 2 ASSTS TO DOSIK; PROT SUBM 2/21/84				
L Apr-10-85		AMENDMENT	85-10	DJF		850310
		(a) CV,CKLST PT9 /003-076-008 PROT SUBM 1/18/85 STRUM, STEPHEN B CA-SOLID; COMPASSIONATE				

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
L Apr-15-85		AMENDMENT	85-11	DJF		850313
		(a) CKLST,PROT,CV-ASSOC(s) PT9 /003-074-022 PROT SUBM 2/21/84, AMND 9/26/84; CV SUBM 8/14/84 MOORE,JOSEPH O ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
		(b) DRUG EXPERIENCE RPT PT10 /003-070-001 PT #25: TISSUE NECROSIS				
L Apr-23-85		AMENDMENT	85-12	DJF		850348
		(a) CV(& ASSOCs),CKLST PT9 /003-076-009 PROT SUBM 1/18/85 GOTTLEIB,ROBERT J CA-SOLID; COMPASSIONATE				
		(b) /003-071-0 BERKOWITZ (CV SUBM 8/24/84) ADDED AS ASST INVESTIGATOR				
L May-10-85		AMENDMENT	85-13	DJF		850459
		(a) CV,CKLST PT9 /003-076-010 PROT SUBM 1/18/85 ROBERTS,JOHN CA-SOLID; COMPASSIONATE				
		(b) CV(& ASSOCs),CKLST,PROT PT9,10 /003-079-001 SRIDHAR,KASI CA-HEAD & NECK				
		(c) CV(& ASSOCs),CKLST,PROT PT9,10 /003-080-001 KELSEN,DAVID CA-STOMACH				
L May-14-85		AMENDMENT	85-14	DJF		850468

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(a) CV,CKLST PT9a /003-076-011 PROT SUBM 1/18/85 KOO,VICTOR S CA-SOLID; COMPASSIONATE			
		(b) CV(& ASSOCs),CKLST PT9b /003-077-004 PROT SUBM 1/18/85 FORTE,FRANCIS A LEUKEMIA; COMPASSIONATE			
L May-15-85		AMENDMENT	85-15	DJF	850469
		(a) CV(& ASSOCs),CKLST PT9 /003-077-003 PROT SUBM 1/18/85 ALBALA,MAURICE LEUKEMIA; COMPASSIONATE			
L May-21-85		AMENDMENT	85-16	DJF	850473
		(a) CKLST PT9 /003-076-012 PROT SUBM 1/18/85; CV(& ASSOCs) SUBM 5/14/85 FORTE,FRANCIS A CA-SOLID; COMPASSIONATE			
L May-24-85		AMENDMENT	85-17	DJF	850440
		(a) CKLST # /PT 9 CURRENTLY ACTIVE INVESTIGATORS (AS OF 4/15/85)			
		(b) PROGRESS RPT # /PT 10 ABRAMSON,NEIL ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) ALBERTS,DAVID S CA-OV,COLON; DOSE RANGING PK OF IP ADMINISTRATION ALLEGRA/WOODCOCK CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS AMARE LEUKEMIA			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

ARLIN,ZALMEN A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
ARLIN,ZALMEN A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
ARLIN,ZALMEN A
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
ARLIN,ZALMEN A
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION
ARLIN,ZALMEN A
LEUKEMIA

ARLIN,ZALMEN A
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
ARMENTROUT,STEVEN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
ARMENTROUT,STEVEN
LEUKEMIA

ARMENTROUT,STEVEN
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
BENIGNO,BENEDICT R
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
BENNETT,J/QAZI,RAMAN
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
BENNETT,J/QAZI,RAMAN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
BERNARD,STEPHEN A
CA-LUNG
WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA
BERNARD,STEPHEN A
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
BERNARD,STEPHEN A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

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BERNHARDT, BERNARD
BITRAN, JACOB / GOLOMB
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
BLOCK
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
BLUMING, AVRUM Z
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
BRODORSKY
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
BROUN, GORONWY O
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
BROUN, GORONWY O
LEUKEMIA

BYRNE
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
CASE, DELVYN C
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
CASE, DELVYN C
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
CASE, DELVYN C
LYMPHOMA
NON-HODGKIN'S
CASSILETH
LEUKEMIA

CHLEBOWSKI
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION
CHLEBOWSKI
HEPATOMA

COHEN, RICHARD J
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
CONRAD, MARCEL E
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

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CONRAD, MARCEL E
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
COOPER, MILES R
LEUKEMIA; COMPASSIONATE

COSTANZI, JOHN J
LYMPHOMA
NON-HODGKIN'S
DAO
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
DENEFRIO, JOHN M
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
DENEFRIO, JOHN M
CA-SOLID; COMPASSIONATE

DESAI
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
DESSER, R K
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
DOROSHOW
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
DOSIK, HARVEY
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
DOSIK, MICHAEL H
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
DOTY, GORDON L
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
DOTY, GORDON L
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
DOTY, GORDON L
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
DRESDNER, DAVID M
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

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DRESDNER, DAVID M
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
DUGAN
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
ERSLEV, ALLAN J
LEUKEMIA

ERSLEV, ALLAN J
LYMPHOMA
NON-HODGKIN'S
FASS, LEROY
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
GABRIEL, DON A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
GABRIEL, DON A
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
GAMS, RICHARD A
LYMPHOMA
NON-HODGKIN'S
GAMS, RICHARD A
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
GAMS, RICHARD A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
GAMS, RICHARD A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
GAMS, RICHARD A
LEUKEMIA

GEORGE, SEBASTIAN
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
GEORGE, SEBASTIAN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
GOLOMB, HARVEY M
LYMPHOMA
NON-HODGKIN'S

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GOODMAN,GARY E
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
GRACE,WILLIAM R
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
GRACE,WILLIAM R
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
GRILLO,JAMES
CA-SOLID; COMPASSIONATE

GROPPE,CARL W
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
HEIM,WILLIAM J
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
HENDERSON,I CRAIG
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION
HESKETH,PAUL
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
HICKS,WILLIAM J
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
HOLLAND,JAMES
LEUKEMIA

HOLLAND,JAMES F
HOLLAND,JAMES F
ALL
COMBINED w/ VINCRISTINE & DEXAMETHASONE
HOLLAND,JAMES F
LYMPHOMA
COMBINED w/ VINCRISTINE & DEXAMETHASONE
HOLROYDE,CRISTPHER P
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
HORVATH,WILLIAM L
CA-SOLID; COMPASSIONATE

JAFFREY,IRA S
CA-SOLID; COMPASSIONATE

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JAFFREY,IRA S
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
JONES,ROY
CA-BREAST; DOSE RANGING
ESCALATING DOSE -CARDIAC MEASUREMENTS
JONES,STEPHEN E
LYMPHOMA
NON-HODGKIN'S
KARP,DANIEL D
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
KENNEDY,PETER S
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
KLOSS,ROBERT A
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
KRAKOFF,I H
KRAKOFF,I H
CA-BREAST
COMB w/ CYCLOPHOS, 5-FU X-OVER TO
ADRIAMYCIN/VINBLASTINE
KREMENTZ,EDWARD T
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
KREMENTZ,EDWARD T
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
LAWSON
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
LEVICK
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
LEVINE,JAMES D
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
LOWENBRAUN,STANLEY
CA-SOLID; COMPASSIONATE

MABRY,R JAMES
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
MOORE,JOSEPH O
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS

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MOORE,JOSEPH O
CA-LUNG
WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA
MOORE,JOSEPH O
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
MOORE,JOSEPH O
LEUKEMIA

MORGAN,LEE ROY
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
MUGGIA,FRANCO
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
MUSS
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
McFARLAND,JAMES A
LEUKEMIA; COMPASSIONATE

OISHI,NOBORU
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PETERSEN
LYMPHOMA
NON-HODGKIN'S
PLOTKIN,DAVID
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PORTLOCK,CAROL S
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PRESANT,CARY A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
QAZI,RAMAN
RIVKIN,SAUL E
LYMPHOMA
NON-HODGKIN'S

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ROACH,RALPH W
ROBINSON,WILLIAM
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
ROSS
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
SAMUELS,ARTHUR J
SARG,MICHAEL J
CA-LUNG
WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA
SARTIANO,GEORGE P
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
SARTIANO,GEORGE P
LEUKEMIA

SCHADE,STANLEY G
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
SCHER,NANCY
CA-SOLID; COMPASSIONATE

SCHWARTZ,I ROBERT
LEUKEMIA

SCOTT,ROBERT B
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
SEBASTIAN,GEORGE
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
SHAW,JOHN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
SILVER,RICHARD T
LYMPHOMA
NON-HODGKIN'S
SILVER,RICHARD T
LEUKEMIA

SILVER,RICHARD T
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
SILVER,RICHARD T
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

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SPAULDING, MONICA B
SPICER
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
STEIN, RICHARD S
LYMPHOMA
NON-HODGKIN'S
STEIN, RICHARD S
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
STONE, LAWRENCE A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
STRUM, STEPHEN B
CA-SOLID; COMPASSIONATE

STUART, JOHN J
LYMPHOMA
NON-HODGKIN'S
STUART, JOHN J
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
TRANUM, BILL L
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
TRUMP, DONALD L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
VILLA, LUIS
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
VOGEL, CHARLES L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
VOLBERDING
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
VOYCE, GARY F
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WACHI, DENNIS H
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WEAVER, ZEBULON III
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

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WEAVER,ZEBULON III
CA-SOLID; COMPASSIONATE

WEIDEN
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WEINTRAUB,LEWIS R
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

WHITE
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
WHITE,CHARLES F
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WHITE,CHARLES F
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WIERNIK,PETER H
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WIERNIK,PETER H
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
WIERNIK,PETER H
LEUKEMIA

WOLFF,STEVEN N
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
WOLFF,STEVEN N
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WOLFF,STEVEN N
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WOODCOCK,THOMAS M
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION
WOODCOCK,THOMAS M
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

(c) TOXICOLOGY STUDIES # /PT 10
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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L May-29-85		AMENDMENT	85-18	DJF	850512
		(a) CV(& ASSOCs),CKLST PT9a /003-076-014 COMPASSIONATE PROT (SOLID TUMORS) SUBM 1/18/85 NELSON,ERIC C CA-SOLID; COMPASSIONATE			
		(b) CV(& ASSOCs),CKLST PT9b /003-077-005 COMPASSIONATE PROT (LEUKEMIA) SUBM 1/18/85			
L May-30-85		AMENDMENT	85-19	DJF	850511
		(a) CV-ASSOC(s) PT9 /003-074-015 CV FOR DR S ROTHENBERG; PROT SUBM 2/21/84, AMENDED 8/24/84			
L Jun-03-85		AMENDMENT	85-20	DJF	850533
		(a) CV,CKLST PT9 /003-046-003 MILLER REPLACES JONES AS PRINC INVEST; PROT SUBM 12/8/82 JONES,STEPHEN E LYMPHOMA NON-HODGKIN'S MILLER,THOMAS /JONES LYMPHOMA NON-HODGKIN'S			
L Jun-25-85		AMENDMENT	85-21	DJF	850599
		(a) CV-ASSOC(s) PT9a /003-048-028 7 ASSOCS; PROT SUBM 2/21/84			
		(b) CV,CKLST PT9b /003-076-015 COMPASSIONATE PROT SUBM 1/18/85 ARENA,PAUL CA-SOLID; COMPASSIONATE			
		(c) CV,CKLST PT9b /003-076-017 COMPASSIONATE PROT SUBM 1/18/85			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		BUDD, THOMAS G CA-SOLID; COMPASSIONATE			
		(d) CV(& ASSOCs), CKLST PT9c /003-077-006 COMPASSIONATE PROT SUBM 1/18/85 SAUNDERS, DARRELL F LEUKEMIA; COMPASSIONATE			
		(e) CV(& ASSOCs), CKLST PT9d /003-044-000 (ONE PT) FOLLOWING MITO TRTMT SECT OF LEUK PROT SUBM 9/10/82 ALGAZY, KENNETH M LEUKEMIA			
L Jun-26-85		AMENDMENT	85-22	DJF	850606
		(a) CV(& ASSOCs), CKLST, PROT PT9,10 /003-079-002 ERVIN, THOMAS CA-HEAD & NECK			
L Jul-08-85		AMENDMENT	85-23	DJF	850659
		(a) CV(& ASSOCs), CKLST PT9 /003-080-002 PROT SUBM 5/10/85 BENEDETTO, PASQUALE CA-STOMACH			
L Jul-31-85		AMENDMENT	85-24	DJF	850700
		(a) CV-ASSOC(s) PT9 /003-079-002 2 ASSOCs TO ERVIN (#187); PROT SUBM 6/26/85			
		(b) PROTOCOL AMENDMENT PT10 /003-072-000 A#1: OPTIONAL TESTS; PROT SUBM 12/13/83			
		(c) PROTOCOL AMENDMENT PT10 /003-072-000 A#2: MISCELLANEOUS CHANGES; PROT SUBM 12/13/83			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
L Aug-02-85		AMENDMENT	85-25	DJF		850769
		(a) CV(& ASSOCs),CKLST PT9ab /003-072-005 UPDATED CVs (PROT SUBM 12/13/83, AMENDED I&II 7/31/85) CASE,DELVYN C CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION				
L Aug-06-85		AMENDMENT	85-26	DJF		850753
		(a) PROTOCOL AMENDMENT PT10a /003-046-010 A #2A: MUGA SCAN OR ECHO ALLOWED (PROT SUBM 12/8/82)				
		(b) PROTOCOL AMENDMENT PT10b /003-071-030 A #1A: MUGA SCAN OR ECHO ALLOWED (PROT SUBM 2/21/84)				
L Aug-07-85		AMENDMENT	85-27	DJF		850755
		(a) PROTOCOL AMENDMENT PT10 /003-074-000 A#2: NO CNS LEUK AT BASELINE (PROT SUBM 2/21/84)				
L Aug-12-85		AMENDMENT	85-28	DJF		850791
		(a) CV,CKLST PT9 /003-076-019 PROT SUBM 1/18/85 SMITH,FREDERICK P CA-SOLID; COMPASSIONATE				
L Aug-16-85		AMENDMENT	85-29	DJF		850803
		(a) CV,CKLST PT9 /003-076-022 UPDATED CV; PROT SUBM 1/18/85 BERTINO,JOSEPH CA-SOLID; COMPASSIONATE				

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Aug-21-85		AMENDMENT	85-30	DJF	850811
		(a) CV(& ASSOCs),CKLST PT9a /003-076-023 PROT SUBM 1/18/85 VERDIRAME,JOSEPH CA-SOLID; COMPASSIONATE			
		(b) CV-ASSOC(s) PT9b /003-079-001 4 ASSTs TO SRIDHAR (#178); CV & PROT SUBM 5/10/85			
		(c) CV-ASSOC(s) PT9b /003-080-002 4 ASSTs TO BENEDETTO (#191 CV SUBM 7/8/85);PROT SUBM 5/10/85			
L Sep-03-85		AMENDMENT	85-31	DJF	850865
		(a) CKLST PT9a /003-076-020 PROT SUBM 1/18/85; CV(& ASSOCs) SUBM 5/29/85 PAPISH,STEPHEN W CA-SOLID; COMPASSIONATE			
		(b) CV,CKLST PT9b /003-076-025 PROT SUBM 1/18/85 KUBOTA,THOMAS T CA-SOLID; COMPASSIONATE			
L Sep-05-85		AMENDMENT	85-32	DJF	850866
		(a) CV,CKLST PT9 /003-077-007 UPDATED CV; PROT SUBM 1/18/85 STUART,JOHN LEUKEMIA; COMPASSIONATE			
L Sep-06-85		AMENDMENT	85-33	DJF	850760
		(a) DRUG EXPERIENCE RPT PT10 /003-070-001 (FOLL UP TO 4/15/85 RPT) PT#25: TISSUE NECROSIS			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(b) DRUG EXPERIENCE RPT # /PT 10 (AUSTRALIA - COMPASSIONATE PT) TISSUE NECROSIS			
L Sep-23-85		AMENDMENT	85-34	DJF	850840
		(a) CV(& ASSOCs),CKLST PT9a /003-077-010 PROT SUBM 1/10/85			
		(b) DRUG EXPERIENCE RPT # /PT 10 (WG) DEATH: OVERDOSE EFFECT; APLASIA BONE MARROW KOWAL-VERN,ARETA LEUKEMIA; COMPASSIONATE			
L Sep-25-85		AMENDMENT	85-35	DJF	850965
		(a) CV,CKLST PT9 /003-076-018 PROT SUBM 1/18/85 SCHELL,FRANK CJ CA-SOLID; COMPASSIONATE			
		(b) PROTOCOL PT10a /003-075-000 FINAL COPY OF PROTOCOL, ORIGINALLY SUBM 2/22/84			
		(c) PROTOCOL AMENDMENT PT10b /003-075-000 A#2: DOSAGE ADJUSTMT; PROT (RE)SUBM 9/25/85, A#1 - 2/19/85			
L Oct-11-85		AMENDMENT	85-36	DJF	850967
		(a) CV,CKLST PT9 /003-077-009 PROT SUBM 1/18/85 DENHAM,CLAUDE A LEUKEMIA; COMPASSIONATE			
L Oct-16-85		AMENDMENT	85-37	DJF	850974
		(a) CV,CKLST PT9a /003-077-011 UPDATED CV; PROT SUBM 1/18/85 ARLIN, ZALMEN A LEUKEMIA; COMPASSIONATE			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(b) CV-ASSOC(s) PT9b /003-077-007 FOR 9 ASST INVESTIGATORS; PROT SUBM 1/18/85			
L Oct-23-85		AMENDMENT	85-39	DJF	851018
		(a) SUMMARY, PRECLINICAL # /PT 6 ACUTE INTRAVESICULAR & INTRAPERITONEAL STUDIES IN DOGS			
		(b) CV,CKLST,PROTO PT9 /003-082-001 DP3-78 REV'd/RESUBM'd 1/13/86 AS DP3-82; ALBERTS' CV 2/22/84 ALBERTS,DAVID S CA-BLADDER; DOSE RANGING INTRAVESIC ADMIN; DP3-78 REV'd & RESUBM'd 1/10/86 AS DP3-82			
L Oct-23-85		AMENDMENT	85-38	DJF	851007
		(a) CV-ASSOC(s) PT9 /003-037-001 FOR LOCKER, TREATING PT #35 WHO MOVED FROM UCLA TO ILLINOIS			
L Oct-25-85		AMENDMENT	85-40	DJF	851035
		(a) INVESTIGATOR BROCHURE # /PT 7 ISSUE DATE 10/15/85			
L Oct-30-85		AMENDMENT	85-41	DJF	850969
		(a) CV,CKLST PT9a /003-076-033 PROT SUBM 1/18/85 DEUR,CHARLES J CA-SOLID; COMPASSIONATE			
		(b) CV,CKLST PT9b /003-076-026 UPDATED CV; PROT SUBM 1/18/85 MUGGIA,FANCO CA-SOLID; COMPASSIONATE			
		(c) CV,CKLST PT9c /003-076-024 PROT SUBM 1/18/85			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		WALLACE, JAMES H CA-SOLID; COMPASSIONATE				
		(d) CV, CKLST PT9d /003-077-012 PROT SUBM 1/18/85 De GREEN, PETER LEUKEMIA; COMPASSIONATE				
		(e) CV(& ASSOCs), CKLST PT9e /003-077-013 PROT SUBM 1/18/85 SCHECTER, GERALDINE LEUKEMIA; COMPASSIONATE				
		(f) DRUG EXPERIENCE RPT PT10 /003-044-002 PT # 5035 DEATH: JAUNDICE				
L Nov-04-85		AMENDMENT	85-42	DJF		851093
		(a) CV(& ASSOCs), CKLST PT9 /003-046-006 WHEELER REPLACES GAMS AS PRINC INVEST; PROT SUBM 12/8/82 GAMS, RICHARD A LYMPHOMA NON-HODGKIN'S WHEELER, RICHARD LYMPHOMA NON-HODGKIN'S				
		(b) CV(& ASSOCs), CKLST PT9 /003-044-008 WHEELER REPLACES GAMS AS PRINC INVEST; PROT SUBM 9/10/82 GAMS, RICHARD A LEUKEMIA WHEELER, RICHARD LEUKEMIA				
L Nov-11-85		AMENDMENT	85-43	DJF		851101
		(a) CV(& ASSOCs), CKLST PT9 /003-076-032 COMPASSIONATE PROT SUBM 1/18/85				

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16,332	IND	MITOKANTRONE CL 232,315	ANTICANCER AGENT		

FIELDER, KATHLEEN
CA-SOLID; COMPASSIONATE

L Nov-14-85		AMENDMENT	85-44	DJF	851094
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- (a) CV, CKLST
PT9a /003-076-037
COMPASSIONATE PROT SUBM 1/18/85
ROSS, MICHAEL
CA-SOLID; COMPASSIONATE
- (b) CKLST
PT9b /003-048-013
WHEELER (CV SUBM 11/4/85) REPLACES GAMS; PROT SUBM 2/14/83
GAMS, RICHARD A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WHEELER, RICHARD
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
- (c) CKLST
PT9b /003-071-028
WHEELER (CV SUBM 11/4/85) REPLACES GAMS; PROT SUBM 2/21/84
GAMS, RICHARD A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WHEELER, RICHARD
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
- (d) CKLST
PT9b /003-074-011
WHEELER (CV & ASSOCS' SUBM 11/4/85) REPL GAMS;
PROT 2/21/84
GAMS, RICHARD A
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
WHEELER, RICHARD
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Nov-18-85		AMENDMENT	85-45	DJF	851104
		(a) CV(& ASSOCs),CKLST PT9a /003-076-034 COMPASSIONATE PROT SUBM 1/18/85 DANNEMAN,Wm G CA-SOLID; COMPASSIONATE			
		(b) CV(& ASSOCs),CKLST PT9b /003-077-014 COMPASSIONATE PROT SUBM 1/18/85 STRAUSS,JAMES F LEUKEMIA; COMPASSIONATE			
F Nov-18-85		REQUIREMENT FDA REQUIRES LED TO SUBMIT PAST PROGRESS REPORTS		DJF	851136
L Nov-21-85		AMENDMENT	85-46	DJF	851116
		(a) CKLST PT9 /003-076-035 CV SUBM 7/9/82; ASSOC CVs SUBM 7/9/82,10/27/83; PROT 1/18/85 LEVICK,STANLEY N CA-SOLID; COMPASSIONATE			
L Nov-26-85	F Nov-18-85	CORRESPONDENCE LED IS INDEED UP TO DATE IN FILING PROGRESS REPORTS	85-47	DJF	851137
L Dec-09-85		AMENDMENT	85-49	DJF	851176
		(a) CV,CKLST PT9 /003-076-028 CV SUBM 3/11/85; PROT SUBM 1/11/85 McFARLAND,JAMES A CA-SOLID; COMPASSIONATE			
		(b) CV,CKLST PT9 /003-076-046 CV SUBM 4/25/84; PROT SUBM 1/11/85			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		BENNETT,JOHN M CA-SOLID; COMPASSIONATE				
L Dec-12-85		AMENDMENT	85-50	DJF		851192
		(a) CV,CKLST PT9 /003-076-044 PROT SUBM 1/11/85 BALA,AYER CA-SOLID; COMPASSIONATE				
		(b) CV(& ASSOCs),CKLST PT9 /003-076-045 PROT SUBM 1/11/85 PANDYA,KISHAN J CA-SOLID; COMPASSIONATE				
L Dec-16-85		AMENDMENT	85-51	DJF		851214
		(a) CV,CKLST PT9a /003-077-018 PROT SUBM 1/11/85 (UPDATED CV) SILVER,RICHARD T LEUKEMIA; COMPASSIONATE				
		(b) CV,CKLST PT9b /003-076-051 PROT SUBM 1/11/85 HENDERSON,CHARLES A CA-SOLID; COMPASSIONATE				
L Dec-23-85		AMENDMENT	85-53	DJF		851217
		(a) CV(& ASSOCs),CKLST PT9 /003-074-025 PROT SUBM 2/21/84 RUBIN,ARNOLD D ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
L Jan-03-86		AMENDMENT	86-1	DJF		860011
		(a) CV # /PT 9 CV FOR DR S SALETAN WHO REPLACES DUKART AS LED MONITOR				

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		(b) PROTOCOL AMENDMENT PT10 /003-072-000 A#3: DELETION OF PK ANALYSES; PROT SUBM 12/13/83				
L Jan-13-86		AMENDMENT	86-1	DJF		860547
		(a) PROTOCOL PT10 /003-082-001 PROT REVISED (WAS 3-78) BASED ON TOXICITIES FROM CANADA STUD				
L Jan-15-86		AMENDMENT	86-2	DJF		860548
		(a) CV(& ASSOCS),CKLST PT9 /003-077-015 GRONCY,PAULA LEUKEMIA; COMPASSIONATE				
L Jan-17-86		AMENDMENT	86-3	DJF		860549
		(a) CV(& ASSOCS),CKLST PT9 /003-074-026 PROT SUBM 2/21/84 KATTLOVE,HERMAN ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
L Jan-29-86		AMENDMENT	86-4	DJF		860077
		(a) CV,CKLST PT9a /003-076-021 PROT SUBM 1/11/85 PETERSON,JAY T CA-SOLID; COMPASSIONATE				
		(b) CV,CKLST PT9b /003-077-019 PROT SUBM 1/11/85 HANSON,JOHN P LEUKEMIA; COMPASSIONATE				
L Feb-03-86		AMENDMENT	86-5	DJF		860092
		(a) CV,CKLST PT9a /003-076-049 PROT SUBM 1/11/85				

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		SCHREEDER, MARSHALL T CA-SOLID; COMPASSIONATE			
		(a) CV, CKLST PT9b /003-076-043 PROT SUBM 1/11/85 SCHREEDER, MARSHALL T CA-SOLID; COMPASSIONATE			
L Feb-05-86		AMENDMENT	86-6	DJF	860096
		(a) CKLST PT9 /003-072-006 PROT SUBM 12/3/83; CV(& ASSOCS) SUBM 11/4/85 WHEELER, RICHARD H CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION			
L Feb-05-86		AMENDMENT	86-7	DJF	860095
		(a) CV, CKLST PT9a /003-076-050 PROT SUBM 1/11/85 ALAVI, JANE B CA-SOLID; COMPASSIONATE			
		(b) CV, CKLST PT9b /003-076-052 PROT SUBM 1/11/85 BLOW, ALTON J CA-SOLID; COMPASSIONATE			
L Feb-18-86		AMENDMENT	86-8	DJF	860116
		(a) CV(& ASSOCS), CKLST PT9 /003-074-027 PROT SUBM 2/21/84 BICKERS, JOHN N ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Feb-19-86		AMENDMENT	86-9	DJF	860102
		(a) CV, CKLST PT9a /003-076-054 PROT SUBM 1/11/85			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		FEINER,ALAN S CA-SOLID; COMPASSIONATE			
		(b) CV,CKLST PT9a /003-076-062 PROT SUBM 1/11/85 FREDRIC,RHETT K CA-SOLID; COMPASSIONATE			
1 Feb-25-86		AMENDMENT	86-11	DJF	860148
		(a) CV(& ASSOCs),CKLST PT9 /003-076-048 PROT SUBM 1/1/86 HARRIS, WILLIAM KING,GERALD W CA-SOLID; COMPASSIONATE			
1 Feb-25-86		CORRESPONDENCE	86-10	DJF	860159
		FDA AUTH'd TO X-REF IND FOR COOPER,STUART&PACIUCCI's FILING			
1 Mar-19-86		AMENDMENT	86-12	DJF	860215
		LED PROPOSAL FOR EXPEDITING USE OF MITO ON COMPASSION BASIS			
1 Mar-19-86		AMENDMENT	86-13	DJF	860216
		(a) CKLST PT9a /003-076-036 GRACE'S CV SUBM 7/13/82; PROT SUBM 1/11/85 GRACE,WILLIAM R CA-SOLID; COMPASSIONATE			
		(b) CV,CKLST PT9b /003-076-040 PROT SUBM 1/11/85 ENGELBERG,CHARLES B CA-SOLID; COMPASSIONATE			
		(c) CV(& ASSOCs),CKLST PT9c /003-077-016 PROT SUBM 1/11/85			

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16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		
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O'CONNELL, JOSEPH
 LEUKEMIA; COMPASSIONATE

L Mar-20-86		AMENDMENT	86-15	DJF	860218
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- (a) CV, CKLST
 PT9a /003-077-024
 PROT SUBM 1/11/85
 SENEAL, FRANCIS M
 LEUKEMIA; COMPASSIONATE
- (b) CKLST, CV-ASSOC(s)
 PT9b /003-077-026
 DESAI'S CV SUBM 11/18/85; PROT SUBM 1/11/85
 DESAI, AJIT M
 LEUKEMIA; COMPASSIONATE
- (c) CV, CKLST
 PT9c /003-077-032
 PROT SUBM 1/11/85
 MEARS, J GREGORY
 LEUKEMIA; COMPASSIONATE

L Mar-20-86		AMENDMENT	86-14	DJF	860217
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- (a) CV(& ASSOCs), CKLST
 PT9a /003-076-047
 PROT SUBM 1/11/85
 GOODWIN, J WENDALL
 CA-SOLID; COMPASSIONATE
- (b) CV, CKLST
 PT9b /003-076-053
 PROT SUBM 1/11/85
 STALLINGS, LAWRENCE M
 CA-SOLID; COMPASSIONATE
- (c) CV, CKLST
 PT9c /003-076-061
 PROT SUBM 1/11/85
 McMAHON, RICHARD T
 CA-SOLID; COMPASSIONATE

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16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT			
L Mar-21-86		AMENDMENT	86-16	DJF		860219
		(a) CV,CKLST PT9 /003-076-072 PROT SUBM 1/11/85 McKEOWN,JOHN M CA-SOLID; COMPASSIONATE				
L Mar-31-86		AMENDMENT	86-17	DJF		860263
		(a) CV(& ASSOCs),CKLST PT9 /003-072-007 PROT SUBM 12/13/83 BENNETT,JOHN M CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION				
		(b) PROTOCOL AMENDMENT PT10 /003-075-001 A#3: ALLOWS FOR CONTINUOUS (UNDRAINED) DWELL TIME				
L Apr-09-86		AMENDMENT	86-18	DJF		860550
		(a) CV(& ASSOCs),CKLST,PROT PT9,10 /003-081-001 HOLLAND,JAMES F CA-BREAST PHS I&II. COMBINATION OF NOVANTRONE w THIOTEPA &METHOTREXATE				
L Apr-10-86		AMENDMENT	86-19	DJF		860339
		(a) CV(& ASSOCs),CKLST PT9a /003-076-030 PROT SUBM 1/11/85 BEARDEN,JAMES D III CA-SOLID; COMPASSIONATE				
		(b) CV(& ASSOCs),CKLST PT9b /003-076-065 PROT SUBM 1/11/85 NOMANBHOY,YUNUS T CA-SOLID; COMPASSIONATE				

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16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		
1 Apr-15-86		AMENDMENT	86-20	DJF	860341
	(a)	CV,CKLST PT9 /003-076-060 PROT SUBM 1/11/85 HAROLD,SUSAN E CA-SOLID; COMPASSIONATE			
1 May-20-86		AMENDMENT	86-21	DJF	860493
	(a)	CV(& ASSOCS),CKLST PT9 /003-074-028 PROT SUBM 2/21/84 STEIN,RICHARD S ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
1 May-27-86		AMENDMENT	86-22	DJF	860512
	(a)	CV,CKLST PT9 /003-074-029 PROT SUBM 2/21/84 DARA,PARVEZ ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
1 Jun-06-86		AMENDMENT	86-23	DJF	860551
	(a)	CV PT9a /003-082-001 UPDATED CV FOR ALBERTS & STANISIC (WHO IS NOW ASSOC INVESTR)			
	(b)	CV(& ASSOCS),CKLST PT9b /003-082-002 PROT SUBM 1/13/86 SHARIFI,R /LAMB,D CA-BLADDER; DOSE RANGING INTRAVESIC ADMIN; DP3-78 REV'd & RESUBM'd 1/10/86 AS DP3-82			
1 Jun-25-86		AMENDMENT	86-23	DJF	860612
	(a)	CKLST # /PT 9 LIST OF CURRENTLY ACTIVE INVESTIGATORS			

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(b) PROGRESS RPT # /PT 10a
ALSO, REFER TO SAFETY UPDATE SUBM'd 2/25/86 TO NDA
19-297

AHR, DAVID
CA-SOLID; COMPASSIONATE

ALAVI, JANE B
CA-SOLID; COMPASSIONATE

ALBALA, MAURICE
LEUKEMIA; COMPASSIONATE

ALI, I
LEUKEMIA; COMPASSIONATE

ALLEGRA/WOODCOCK
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
AMARE
LEUKEMIA

ARENA, PAUL
CA-SOLID; COMPASSIONATE

ARLIN, ZALMEN A
LEUKEMIA; COMPASSIONATE

ARLIN, ZALMEN A
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
ARMENTROUT, STEVEN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
ASBURY, ROBERT
CA-SOLID; COMPASSIONATE

BABCOCK, Wm
LEUKEMIA; COMPASSIONATE

BALA, AYER
CA-SOLID; COMPASSIONATE

BEARDEN, JAMES D III
CA-SOLID; COMPASSIONATE

BENEDETTO, PASQUALE
CA-STOMACH

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BENIGNO,BENEDICT R
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
BENJAMIN,ROBERT
CA-SOLID; COMPASSIONATE

BENNETT,JOHN M
CA-SOLID; COMPASSIONATE

BERNARD,STEPHEN A
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
BERNARD,STEPHEN A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
BERTINO,JOSEPH
CA-SOLID; COMPASSIONATE

BIRDWELL,ROBERT
CA-SOLID; COMPASSIONATE

BITRAN,JACOB /GOLOMB
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
BLOCK
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
BLOW,ALTON J
CA-SOLID; COMPASSIONATE

BLUMING,AVRUM Z
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
BRADY,ALBERT
CA-SOLID; COMPASSIONATE

BRODORSKY
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
BUDD,THOMAS G
CA-SOLID; COMPASSIONATE

BURTON,GARY
LEUKEMIA; COMPASSIONATE

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CASIMIR, MIRTHA
CA-SOLID; COMPASSIONATE

CHLEBOWSKI
HEPATOMA

CHU, ALBERT
LEUKEMIA; COMPASSIONATE

COLEMAN, MORTON
CA-SOLID; COMPASSIONATE

CONRAD, MARCEL E
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
CONRAD, MARCEL E
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
COOPER, MILES R
LEUKEMIA; COMPASSIONATE

COSTANZI, JOHN J
LYMPHOMA
NON-HODGKIN'S
CUSTER, GALEN
LEUKEMIA; COMPASSIONATE

CUTTNER, JANET
LEUKEMIA; COMPASSIONATE

DANNEMAN, Wm G
CA-SOLID; COMPASSIONATE

DAO
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
DARA, PARVEZ
CA-SOLID; COMPASSIONATE

DAVIS, HUGH
CA-SOLID; COMPASSIONATE

DEAN, HERBERT
LEUKEMIA; COMPASSIONATE

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DENEFRIO,JOHN M
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
DENEFRIO,JOHN M
CA-SOLID; COMPASSIONATE

DENES,ALEX E
CA-SOLID; COMPASSIONATE

DENHAM,CLAUDE A
LEUKEMIA; COMPASSIONATE

DESAI,AJIT M
LEUKEMIA; COMPASSIONATE

DEUR,CHARLES
LEUKEMIA; COMPASSIONATE

DEUR,CHARLES J
CA-SOLID; COMPASSIONATE

DICKMAN,ELLIOT
CA-SOLID; COMPASSIONATE

DOROSHOW
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
DOTY,GORDON L
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
DOTY,GORDON L
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
DUGAN
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
DeGREEN,PETER
LEUKEMIA; COMPASSIONATE

ENGELBERG,CHARLES B
CA-SOLID; COMPASSIONATE

ERSLEV,ALLAN J
LEUKEMIA

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

FEINER,ALAN S
CA-SOLID; COMPASSIONATE

FIELDER,KATHLEEN
CA-SOLID; COMPASSIONATE

FLETCHER,Wm
CA-SOLID; COMPASSIONATE

FOOTE,SANDRA
CA-SOLID; COMPASSIONATE

FORTE,FRANCIS A
CA-SOLID; COMPASSIONATE

FORTE,FRANCIS A
LEUKEMIA; COMPASSIONATE

FREDRIC,RHETT K
CA-SOLID; COMPASSIONATE

FRIEDMAN,ALLAN
LEUKEMIA; COMPASSIONATE

GEILS,GEORGE
LEUKEMIA; COMPASSIONATE

GEORGE,SEBASTIAN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
GOCKERMAN,JOHN
LEUKEMIA; COMPASSIONATE

GOODMAN,GARY E
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
GOODWIN,J WENDALL
CA-SOLID; COMPASSIONATE

GOTTLEIB,ROBERT J
CA-SOLID; COMPASSIONATE

GRACE,WILLIAM R
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
GRACE,WILLIAM R
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMY N-5FU

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16,332	IND	MITOXANTRONE	CL 232,315	ANTICANCER AGENT	
		GRACE, WILLIAM R			
		CA-SOLID; COMPASSIONATE			
		GRANATIR, ROBERT			
		LEUKEMIA; COMPASSIONATE			
		GRONCY, PAULA			
		LEUKEMIA; COMPASSIONATE			
		HAN, DIN			
		LEUKEMIA; COMPASSIONATE			
		HANSON, JOHN P			
		LEUKEMIA; COMPASSIONATE			
		HANSON, JOHN P			
		CA-SOLID; COMPASSIONATE			
		HANSON, KARL			
		CA-SOLID; COMPASSIONATE			
		HAROLD, SUSAN E			
		CA-SOLID; COMPASSIONATE			
		HENDERSON, CHARLES A			
		CA-SOLID; COMPASSIONATE			
		HENDERSON, I CRAIG			
		CA-BREAST; vs ADRIAMYCIN			
		MULTI-CTR 2nd LINE PTS			
		HESKETH, PAUL			
		CA-BREAST; vs ADRIAMYCIN			
		MULTI-CTR 2nd LINE PTS			
		HOLLAND, JAMES F			
		ALL			
		COMBINED w/ VINCRISTINE & DEXAMETHASONE			
		HOLROYDE, CRISTPHER P			
		LYMPHOMA; vs m-BACOD			
		m-BNCOD COMBO			
		HORVATH, WILLIAM L			
		CA-SOLID; COMPASSIONATE			
		HURD, DAVID			
		CA-SOLID; COMPASSIONATE			
		HYMAN, PAUL			
		CA-SOLID; COMPASSIONATE			

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16,332	IND	MITOXANTRONE	CL 232,315	ANTICANCER AGENT	
		JAFFREY,IRA S CA-SOLID; COMPASSIONATE			
		JAFFREY,IRA S LYMPHOMA; vs m-BACOD m-BNCOD COMBO JIM,ROBERT T.S. LEUKEMIA; COMPASSIONATE			
		JONES,ROY CA-BREAST; DOSE RANGING ESCALATING DOSE -CARDIAC MEASUREMENTS KAJANI,M LEUKEMIA; COMPASSIONATE			
		KAPLAN,BARRY CA-SOLID; COMPASSIONATE			
		KELSEN,DAVID CA-STOMACH			
		KENNEALEY,GERARD CA-SOLID; COMPASSIONATE			
		KING,GERALD W CA-SOLID; COMPASSIONATE			
		KOO,VICTOR S CA-SOLID; COMPASSIONATE			
		KOWAL-VERN,ARETA LEUKEMIA; COMPASSIONATE			
		KRAKOFF,I H CA-BREAST COMB w/ CYCLOPHOS, 5-FU X-OVER TO ADRIAMYCIN/VINBLASTINE KRAKOFF,I H KREMENTZ,EDWARD T CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS KUBOTA,THOMAS T CA-SOLID; COMPASSIONATE			
		LAWSON CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			

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16,332	IND	MITOXANTRONE	CL 232,315	ANTICANCER AGENT	
		LEE, EDWARD LEUKEMIA; COMPASSIONATE			
		LEVICK CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS LEVICK, STANLEY N CA-SOLID; COMPASSIONATE			
		LEVINE, JAMES D LYMPHOMA; vs m-BACOD m-BNCOD COMBO LOCKER, GERSHON CA-SOLID; COMPASSIONATE			
		LOWENBRAUN, STANLEY CA-SOLID; COMPASSIONATE			
		MABRY, R JAMES LYMPHOMA; vs m-BACOD m-BNCOD COMBO MEARS, J GREGORY LEUKEMIA; COMPASSIONATE			
		MENA, PAUL CA-SOLID; COMPASSIONATE			
		MINTON, JOHN CA-SOLID; COMPASSIONATE			
		MOORE, ANN CA-SOLID; COMPASSIONATE			
		MOORE, JOSEPH LEUKEMIA; COMPASSIONATE			
		MOORE, JOSEPH O CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS MORGAN, LEE ROY CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU MUGGIA, FRANCO CA-SOLID; COMPASSIONATE			

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MUSS

CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)

CYCLOPHOSPHAMIDE-N-5FU vs

CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

MYERS,ALAN

CA-SOLID; COMPASSIONATE

McFARLAND,JAMES A

LEUKEMIA; COMPASSIONATE

McFARLAND,JAMES A

CA-SOLID; COMPASSIONATE

McKEOWN,JOHN M

CA-SOLID; COMPASSIONATE

McMAHON,RICHARD T

CA-SOLID; COMPASSIONATE

NELSON,ERIC C

CA-SOLID; COMPASSIONATE

NOMANBHOY,YUNUS T

CA-SOLID; COMPASSIONATE

O'CONNELL,JOSEPH

LEUKEMIA; COMPASSIONATE

PANDYA,KISHAN J

CA-SOLID; COMPASSIONATE

PAPISH,STEPHEN W

LEUKEMIA; COMPASSIONATE

PAPISH,STEPHEN W

CA-SOLID; COMPASSIONATE

PARISER,SANFORD

LEUKEMIA; COMPASSIONATE

PAULSON,STEVEN

LEUKEMIA; COMPASSIONATE

PETERSON,JAY T

CA-SOLID; COMPASSIONATE

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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

PLOTKIN, DAVID
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PORTLOCK, CAROL S
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PRESENT, CARY A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
RIDDICK, DAVID
CA-SOLID; COMPASSIONATE

RIES, CURT
LEUKEMIA; COMPASSIONATE

ROACH, RALPH W
ROBERTS, JOHN
CA-SOLID; COMPASSIONATE

ROEDER, MICHAEL
CA-SOLID; COMPASSIONATE

ROSS
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
ROSS, MICHAEL
CA-SOLID; COMPASSIONATE

ROZEN, SIMON
LEUKEMIA; COMPASSIONATE

RYMER, Wm
CA-SOLID; COMPASSIONATE

SARTIANO, GEORGE P
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
SAUNDERS, DARRELL F
LEUKEMIA; COMPASSIONATE

SCHECTER, GERALDINE
LEUKEMIA; COMPASSIONATE

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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

SCHELL,FRANK CJ
CA-SOLID; COMPASSIONATE

SCHER,NANCY
CA-SOLID; COMPASSIONATE

SCHREEDER,MARSHALL T
CA-SOLID; COMPASSIONATE

SCHWARTZ,JOEL
CA-SOLID; COMPASSIONATE

SEEGER,JARELL
CA-SOLID; COMPASSIONATE

SENECAL,FRANCIS M
LEUKEMIA; COMPASSIONATE

SHAW,JOHN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
SHERMAN,ALFRED I
CA-SOLID; COMPASSIONATE

SHIFTAN,THOMAS
CA-SOLID; COMPASSIONATE

SILVER
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
SILVER,RICHARD T
LEUKEMIA; COMPASSIONATE

SMITH,FREDERICK P
CA-SOLID; COMPASSIONATE

STALLINGS,LAWRENCE M
CA-SOLID; COMPASSIONATE

STASZEWSKI,HARRY
LEUKEMIA; COMPASSIONATE

STEIN,RICHARD S
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
STONE,LAWRENCE A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

STRAUSS, JAMES F
LEUKEMIA; COMPASSIONATE

STUART, JOHN
LEUKEMIA; COMPASSIONATE

TALARICO, LILIA
LEUKEMIA; COMPASSIONATE

THOMAS, PAUL
LEUKEMIA; COMPASSIONATE

VERDIRAME, JOSEPH
CA-SOLID; COMPASSIONATE

VINCEGUERRA, VINCENT
LEUKEMIA; COMPASSIONATE

VOGEL, CHARLES
CA-SOLID; COMPASSIONATE

VOGEL, CHARLES L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
VOLBERDING

CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS

VOYCE, GARY F
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

WACHI, DENNIS H
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

WALLACE, JAMES H
CA-SOLID; COMPASSIONATE

WEAVER, ZEBULON III
CA-SOLID; COMPASSIONATE

WEIDEN
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WEINBERG, BRUCE
LEUKEMIA; COMPASSIONATE

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WHEELER,R (/GAMS)
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WHEELER,RICHARD
LEUKEMIA

WHITE
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
WHITE,CHARLES F
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WHITE,CHARLES F
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WIERNIK,PETER H
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WILBUR,DAVID
CA-SOLID; COMPASSIONATE

WILLIAMS,THOMAS
CA-SOLID; COMPASSIONATE

WOLF,DAVID
LEUKEMIA; COMPASSIONATE

WOLFF,STEVEN N
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
WOLFF,STEVEN N
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WOLFF,STEVEN N
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WOODCOCK,THOMAS M
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WORTMAN,JAMES
CA-SOLID; COMPASSIONATE

ZALUSKY,RALPH
LEUKEMIA; COMPASSIONATE

Led/ Event FIA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOKANTRONE CL 232,315 ANTICANCER AGENT			
		(c) CLINICAL STUDIES PT10b /003-076-000 STATUS OF STUDY DOCUMENTN OF COMPASSION SOLID TUMORS STUDIES			
		(d) CLINICAL STUDIES PT10b /003-077-000 STATUS OF STUDY DOCUMENT'N OF COMPASSIONATE LEUKEMIA STUDIES			
L Jul-03-86	T Jul-01-86	CORRESPONDENCE SUMMARY/LISTING OF LOTS USED IN PRESERV-EFF EVALUATION TESTS		GRP	860764
L Jul-15-86		AMENDMENT	86-25	DJF	860668
		(a) INVESTGTR DOCUMENTN AT LEDERLE PT9 /003-076-000 PROT SUBM 1/11/85			
		(b) INVESTGTR DOCUMENTN AT LEDERLE PT9 /003-077-000 PROT SUBM 1/11/85			
L Aug-05-86		AMENDMENT FDA AUTHd TO X-REF OUR IND TO SUPPORT CAPIZZI's IND FILING	86-26	DJF	870744
L Aug-06-86		AMENDMENT	86-25	DJF	870743
		(a) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-000 LIST OF INVESTGTRs RECEIVING DRUG DURING JULY, '86 BROWN,R.S. CA-SOLID; COMPASSIONATE CARDAMONE,JOSEPH CA-SOLID; COMPASSIONATE HOLLISTER,DICKERMAN LEUKEMIA; COMPASSIONATE LEIBOWITC,R CA-SOLID; COMPASSIONATE LINK,JOHN CA-SOLID; COMPASSIONATE			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE	CL 232,315	ANTICANCER AGENT	
		MUCHMORE, ELAINE CA-SOLID; COMPASSIONATE			
		McDONALD, C CA-SOLID; COMPASSIONATE			
		(b) INVESTGTR DOCUMENTN PENDING PT9 /003-077-000 LIST OF INVSTGTRs RECEIVING DRUG DURING JULY, '86 EYSTER, ELAINE LEUKEMIA; COMPASSIONATE			
		KOPEL, SAM LEUKEMIA; COMPASSIONATE			
		POLMEROY, T. LEUKEMIA; COMPASSIONATE			
		RUBIN, ARNOLD LEUKEMIA; COMPASSIONATE			
		SCHARFMAN, WILLIAM LEUKEMIA; COMPASSIONATE			
		VONHOFF, DANIEL LEUKEMIA; COMPASSIONATE			
F Aug-11-86	L Jul-03-86	REQUIREMENT		GRP	860720
		(a) PRESERVATIVE EFFICACY LED MUST CLARIFY COMPOSITN/MTD OF MANUF FOR FORMULNS 24E, 23R			
L Aug-14-86		AMENDMENT	86-27	DJF	870742
		(a) CKLST PT9 /003-048-001 CKLST FOR DR. GREEN WHO IS REPLACING MUGGIA AS PRINC INVSTGR GREEN, M CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		(b) INVESTIGATOR REPLACEMENT PT9 /003-048-001 MUGGIA REPLACED BY GREEN			

Led/ Event FEA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		MUGGIA,FRANCO CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
L Aug-18-86	F Aug-11-86	CORRESPONDENCE		GRP	860721
		(a) PRESERVATIVE EFFICACY CLARIFICATION OF COMPOSITION/MANUF'g re PRESERV EFF EVALUATN			
L Sep-02-86		AMENDMENT	86-28	DJF	870702
		(a) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-000 LIST OF INVESTIGATORS RECEIVING DRUG DURING AUGUST, '86 BERNARD,STEPHEN CA-SOLID; COMPASSIONATE BRADY,ALBERT CA-SOLID; COMPASSIONATE CHERNOF,DAVID CA-SOLID; COMPASSIONATE CHLEBOWSKI,JOAN CA-SOLID; COMPASSIONATE FLIPPIN,ANTHONY LEUKEMIA; COMPASSIONATE GRUNDBERG,STEVEN CA-SOLID; COMPASSIONATE MANUSZAK,PAUL CA-SOLID; COMPASSIONATE MILLER,DONALD CA-SOLID; COMPASSIONATE OZA,YAGNESH CA-SOLID; COMPASSIONATE RENTSCHLER,ROBERT CA-SOLID; COMPASSIONATE			

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16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		
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SCHNUR,GARY
CA-SOLID; COMPASSIONATE

WORKMAN,FRANK
CA-SOLID; COMPASSIONATE

(b) INVESTGTR DOCUMENTN PENDING
PT9 /003-077-000
LIST OF INVESTIGATORS REC'g EMERGENCY DRUG SHIPMT
IN AUG.'86
ALLAN,STEVE
LEUKEMIA; COMPASSIONATE

BITRAN,JACOB
LEUKEMIA; COMPASSIONATE

BRASS,LAWRENCE
LEUKEMIA; COMPASSIONATE

KATZ,MARTIN
LEUKEMIA; COMPASSIONATE

KELLERMEYER,ROBERT
LEUKEMIA; COMPASSIONATE

(c) INVESTGTR DOCUMENTN at LEDERLE
PT9 /003-077-000
INVESTIGATOR DOCUMENTN NOW ON FILE (PREVIOUSLY
SHIPPED DRUG)
BURTON,GARY
LEUKEMIA; COMPASSIONATE

MOORE,JOSEPH
LEUKEMIA; COMPASSIONATE

WEINBERG,J
LEUKEMIA; COMPASSIONATE

L Sep-09-86

AMENDMENT 86-29 DJF 860828

(a) CV(& ASSDCs),CKLST,PROT
PT9a,10 /003-084-001
CAPIZZI,ROBERT
LEUKEMIA; vs ARA-C, ASPARAGINASE
MITO IN ANLL, ALL, CBL-BL

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(b) CV(& ASSOCs),CKLST,PROT PT9a,10 /003-084-002			
L Oct-01-86		AMENDMENT	86-31	DJF	861028
		(a) CV(& ASSOCs),CKLST PT9 /003-084-003 PROT SUBM 9/9/86 RAAB,STEPHEN LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL			
L Oct-02-86		AMENDMENT	86-30	DJF	860931
		(a) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-115 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 WOZNIK,ANTIONETTE CA-SOLID; COMPASSIONATE			
		(b) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-116 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 PUGH,REGINALD CA-SOLID; COMPASSIONATE			
		(c) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-117 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 LEWIN,MARGARET CA-SOLID; COMPASSIONATE			
		(e) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-118 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 KRONER,JOAN CA-SOLID; COMPASSIONATE			
		(f) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-119 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 BOHNEN,ROBERT CA-SOLID; COMPASSIONATE			
		(g) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-120 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986			

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16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		NICHOLS, CRAIG CA-SOLID; COMPASSIONATE			
		(h) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-121 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 PARKER, BARBARA CA-SOLID; COMPASSIONATE			
		(i) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-122 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 BROWER, MARTIN CA-SOLID; COMPASSIONATE			
		(j) INVESTGTR DOCUMENTN PENDING PT9 /003-077-070 REC'd EMERGENCY DRUG SHIPMENTS 9/86; PROPER DOCUMENTN COMING BHARDWA, SUSHIL LEUKEMIA; COMPASSIONATE			
		(k) INVESTGTR DOCUMENTN PENDING PT9 /003-077-071 REC'd EMERGENCY DRUG SHIPMENTS 9/86; PROPER DOCUMENTN COMING BEDROSE, ANTRANIK LEUKEMIA; COMPASSIONATE			
		(l) INVESTGTR DOCUMENTN PENDING PT9 /003-077-072 REC'd EMERGENCY DRUG SHIPMENTS 9/86; PROPER DOCUMENTN COMING CASSILETH, PETER LEUKEMIA; COMPASSIONATE			
		(m) INVESTGTR DOCUMENTN PENDING PT9 /003-077-073 REC'd EMERGENCY DRUG SHIPMENTS 9/86; PROPER DOCUMENTN COMING OLSON, JOHN LEUKEMIA; COMPASSIONATE			

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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

(a) CV
PT9a /003-082-002
CV FOR LAMB, NEW CO-INVESTIGTR TO SHARIFI; PROT
SUBM 1/10/86
SHARIFI R/ LAMB D
CA-BLADDER; DOSE RANGING
INTRAVESIC ADMIN; DP3-78 REV'd & RESUBM'd
1/10/86 AS DP3-82

(b) CV
PT9b /003-072-002
CV FOR ALI, NEW CO-INVSTGTR TO CHLEBOWSKI; PROT
SUBM 12/3/83
CHLEBOWSKI/ ALI I
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION

(c) CV
PT9c /003-046-002
CV FOR MILLER, NEW CO-INVSGTR TO PETERSON; PROT
SUBM 12/8/82
PETERSON / MILLER
LYMPHOMA
NON-HODGKIN'S

L Cct-21-86		CORRESPONDENCE	86-32	DJF	861034
		FDA AUTH'd TO X-REF IND pts. 1-6 TO SUPPORT CHAMPIN'S FILING			

L Oct-24-86		AMENDMENT	86-33	DJF	860969
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(a) CV(& ASSOCs),CKLST
PT9 /003-084-004
PROT SUBM 9/9/86
TODD,MARY B
LEUKEMIA; vs ARA-C, ASPARAGINASE
MITO IN ANLL, ALL, CBL-BL

L Nov-04-86		AMENDMENT	86-35	DJF	870703
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(a) INVESTGTR DOCUMENTN at LEDERLE/003-076-0
LIST OF INVESTIGATORS REC'g DRUG DURING OCTOBER
'86
BROOKS,BARRY
CA-SOLID; COMPASSIONATE

BUTLER,FRED O
CA-SOLID; COMPASSIONATE

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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

CARPENTER,JOHN
CA-SOLID; COMPASSIONATE

HARWIN,WILLIAM
CA-SOLID; COMPASSIONATE

KISIELIUS,THOMAS
CA-SOLID; COMPASSIONATE

LYSS,ALAN
CA-SOLID; COMPASSIONATE

NEEDLES,BURTON M
CA-SOLID; COMPASSIONATE

RAPHAEL,BRUCE
CA-SOLID; COMPASSIONATE

SPICER,DARCY
CA-SOLID; COMPASSIONATE

(b) INVESTGTR DOCUMENTN PENDING
PT9 /003-077-000
INVESTIGATORS REC'g EMERGENCY DRUG SHIPMENT DURING
OCT.'86
PEMBERTON,CLIFFORD
LEUKEMIA; COMPASSIONATE

PIETRAGALLO,LOUIS
LEUKEMIA; COMPASSIONATE

RAGAB,ABDEL
LEUKEMIA; COMPASSIONATE

SPALDING,MONICA
LEUKEMIA; COMPASSIONATE

(c) INVESTGTR DOCUMENTN at LEDERLE/003-077-0
INVESTIGATOR DOCUMENTN NOW ON FILE (PREVIOUSLY
SHIPPED DRUG)
ALLAN,STEVE
LEUKEMIA; COMPASSIONATE

BRASS,LAWRENCE
LEUKEMIA; COMPASSIONATE

Led/ Event FIA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE	CL 232,315	ANTICANCER AGENT		
		EYSTER,ELAINE LEUKEMIA; COMPASSIONATE				
		FELBER,NORBERT LEUKEMIA; COMPASSIONATE				
		FLIPPIN,ANTHONY LEUKEMIA; COMPASSIONATE				
		HOLLISTER,DICKERMAN LEUKEMIA; COMPASSIONATE				
		SCHARFMAN,WILLIAM LEUKEMIA; COMPASSIONATE				
		VON HOFF,DANIEL LEUKEMIA; COMPASSIONATE				
L Nov-13-86		AMENDMENT	86-37	DJF		870716
		(a) CV(& ASSOCs),CKLST PT9 /003-082-003 DP 3-82 SUBM 1/13/86 SAROSDY,MICHAEL CA-BLADDER; DOSE RANGING INTRAVESIC ADMIN; DP3-78 REV'd & RESUBM'd 1/10/86 AS DP3-82				
L Nov-25-86		AMENDMENT	86-38	DJF		870722
		(a) PHARMACY BROCHURE # /PT 7 UPDATED PHARMACY BROCHURE				
		(b) DER NARRATIVE PT10 /003-075-001 pts# 31-33,35: DEVELOPED INTESTINAL OBSTRUCT (DOSE-LIM TOX)				
L Dec-05-86		AMENDMENT	86-39	DJF		870730
		(a) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-000 RECEIVED EMERGENCY DRUG SHIPMENT DURING NOVEMBER, '86 BERTOLI,JOSEPH CA-SOLID; COMPASSIONATE				

Led/ Event	Cross Ref	Description	Amendment/	Contact Resp Event
FIA Date	Date		Supplement	----- Due ID

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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

CABANILLAS, FERNANDO
CA-SOLID; COMPASSIONATE

CAMPOS, LUIS
CA-SOLID; COMPASSIONATE

HILL, LAWRENCE
CA-SOLID; COMPASSIONATE

POPOVIC, WILLIAM
CA-SOLID; COMPASSIONATE

SPURR, CHARLES
CA-SOLID; COMPASSIONATE

(b) INVESTGTR DOCUMENTN PENDING
PT9 /003-077-000
RECEIVED EMERGENCY DRUG SHIPMENT DURING NOV.'86
GADUZDA, THOMAS
LEUKEMIA; COMPASSIONATE

HINES, JOHN
LEUKEMIA; COMPASSIONATE

HINES, JOHN
LICHTMAN, STUART
LEUKEMIA; COMPASSIONATE

MAZZA, JOSEPH
LEUKEMIA; COMPASSIONATE

NACHANT, NEIL
LEUKEMIA; COMPASSIONATE

ROWE, JACOB
LEUKEMIA; COMPASSIONATE

TISMAN, GLEN
LEUKEMIA; COMPASSIONATE

(c) INVESTGTR DOCUMENTN at LEDERLE
PT9 /003-077-000
DOCUMENTATION NOW ON FILE (PREVIOUSLY SHIPPED
DRUG)
CAPIZZI, ROBERT
LEUKEMIA; COMPASSIONATE

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT		

KELLERMEYER, ROBERT
LEUKEMIA; COMPASSIONATE

- (d) DER NARRATIVE
PT10 /003-075-001
11/25/86 DER SHOULD HAVE CITED OVARIAN CANCER AS
INDICATION

L Jan-20-87

AMENDMENT 87-1 DJF 861315
MONTHLY UPDATE FOR DEC '86 OF COMPASSIONATE USE
3-76,3-77

- (a) INVESTGTR DOCUMENTN at LEDERLE
PT9 /003-076-000
PROTOCOL 3-76 COMPASSIONATE USE / REC'D DEC 86
AJAIKUMAR, B.S.
CA-SOLID; COMPASSIONATE

FURST, ANNETTE
CA-SOLID; COMPASSIONATE

GEERAERTS, LOUIS
CA-SOLID; COMPASSIONATE

LUEDKE, DAN
CA-SOLID; COMPASSIONATE

LUNDBERG W. BRUCE
CA-SOLID; COMPASSIONATE

PATTON, ALLEN
CA-SOLID; COMPASSIONATE

STASZEWSKI, HARRY
CA-SOLID; COMPASSIONATE

TISMAN, GLENN
CA-SOLID; COMPASSIONATE

- (b) INVESTGTR DOCUMENTN PENDING
PT9 /003-077-000
PROTOCOL 3-77 COMPASSIONATE USE
AHMED, FAROUK
LEUKEMIA; COMPASSIONATE

CARTER, PETER
LEUKEMIA; COMPASSIONATE

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp Event ----- Due ID
16,332	IND	MITOXANTRONE	CL-232,315	ANTICANCER AGENT
		CRAUT, ERIC LEUKEMIA; COMPASSIONATE		
		HYMES, KENNETH LEUKEMIA; COMPASSIONATE		
		JHANGANI, HARESH LEUKEMIA; COMPASSIONATE		
		KLEIN, LEONARD LEUKEMIA; COMPASSIONATE		
		KLEIN, LEONARD LEUKEMIA; COMPASSIONATE		
		KNOSPE, WILLIAM LEUKEMIA; COMPASSIONATE		
		RICHMOND, CAROL LEUKEMIA; COMPASSIONATE		
		STOLBERG,LAWRENCE LEUKEMIA; COMPASSIONATE		
		STOLBERG,LAWRENCE LEUKEMIA; COMPASSIONATE		
		ZEHNGEHOT, LEE LEUKEMIA; COMPASSIONATE		
		(c) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-077-000 PROTOCOL 3-77 COMPASSIONATE USE / REC'D DEC 86 BITRAN, JACOB LEUKEMIA; COMPASSIONATE		
		KATZ, MARTIN LEUKEMIA; COMPASSIONATE		
		RUBIN, ARNOLD LEUKEMIA; COMPASSIONATE		

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

STUART, ROBT
LEUKEMIA; vs ARA-C, ASPARAGINASE
MITO IN ANLL, ALL, CBL-BL

1 Feb-25-87

AMENDMENT 87-3 DJF 870083
MTHLY UPDATE FOR JAN '87/COMP. USE PROTS 3-76 /
3-77

- (a) INVESTGTR DOCUMENTN at LEDERLE
/PT 9
PROT 3-76 COMP USE / REC'D JAN '87
- (b) INVESTGTR DOCUMENTN PENDING #
/PT 9
PROT 3-77 COMPASSIONATE USE
- (c) INVESTGTR DOCUMENTN at LEDERLE
/PT 9
PROT 3-77 COMPASSIONATE USE / REC'D JAN '87

1 Mar-06-87

AMENDMENT 87-4 DJF 870089

- (a) CV(& ASSOCs),CKLST,PROT
PT9, 10 /003-087-001
PROTOCOL #3-87 CHEMO-HORMONAL IN ADV BREAST CA
ALLEGRA, JOS. C.
CA-BREAST
COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN
CA-BREAST
REQUESTED BY DR G.BURKE,MRO
EPREMIAN, BARBARA E
CA-BREAST
COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN
CA-BREAST
REQUESTED BY DR G.BURKE,MRO
GENTILE, PATRICK S.
CA-BREAST
COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN
CA-BREAST
REQUESTED BY DR G.BURKE,MRO
HAMM, JOHN T.
CA-BREAST
COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN
CA-BREAST
REQUESTED BY DR G.BURKE,MRO
SEEGER, JANALL
CA-BREAST
COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN
CA-BREAST
REQUESTED BY DR G.BURKE,MRO

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		SHETH, SUBHASH P. CA-BREAST COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN CA-BREAST REQUESTED BY DR G.BURKE,MRO WOODCOCK, THOS, M. CA-BREAST COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN CA-BREAST REQUESTED BY DR G.BURKE,MRO			
L Mar-16-87		CORRESPONDENCE FDA AUTH'D TO X-REF IND FOR PATT'S FILING.	87-5	DJF	870979
		(a) CV PI-YEHUDA PATT PATT, YEHUDA			
L Mar-23-87		AMENDMENT PI- ARNOLD RUBIN	87-6	DJF	870973
		(a) CV(& ASSOCS) PI- ARNOLD RUBIN TREATNG-ACUTE NONLYMPHOCYTIC LEUKEMIA FERNBACH, BARRY ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) RUBIN, ARNOLD ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) YAMUSAH, EMANUEL ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Apr-01-87		CORRESPONDENCE	87-7	DJF	870645
		(a) PRECLINICAL # /PT 10 NOVANTRONE USED TO TREAT HEPATOCELLULAR CARCINOMA RATAIN, MARK J.			
		(b) COMPONENTS & COMPOSITION # /PT 10 HEPATOCELLULAR CARCINOMA			
		(c) CHEMISTRY # /PT 10			
		(d) MANUF & CONTROLS # /PT 10			
		(e) CLINICAL STUDIES # /PT 10			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L May-14-87		AMENDMENT	87-8	DJF	870637
		(a) PROTOCOL AMENDMENT PT10 /003-087-001 RADIONUCLIDE SCAN DNE BE4 TREATMNT CYCL WHEN NOV.> 120MG/M2			
L May-22-87		AMENDMENT	87-9	DJF	870635
		(a) DRUG EXPERIENCE RPT PT10 /003-076-149 OVERDOSE OF NOVANTRONE -FEMALE PAT.-COMP.PROT. BREAST CANCER			
		(b) PROTOCOL PT10 /003-084-000 STUDY WAS STOPPED DUE TO 2 PATIENTS DEATHS			
		(c) TRIAL-SITE(S) CLOSED /003-084-0 STUDY 3-84 (ALL SITES 1-5) DISCONTINUED DUE TO DEATHS CAPIZZI,ROBERT LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL HAMPTON,JAMES W LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL RAAB,STEPHEN LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL STUART, ROBERT LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL TODD,MARY B LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL			
L May-29-87		AMENDMENT	87-10	DJF	870634
		PI- MAURIE MARKMAN-TREATNG OVARIAN CANCER			
		(a) CV # /PT 9 MARKMAN TREATNG PAT.W/OVARIAN CANCER USING INTRAPERITON.RTE. MARKMAN, MAURIE			
		(a) CV PI-MAURIE MARKMAN/TREATNG OVARIAN CANCER,INTRAPERITONEAL RT.			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		MARKMAN, MAURIE				
1 Jun-03-87		AMENDMENT	87-11	DJF		870633
		(a) PROTOCOL AMENDMENT PT10 /003-081-001 PHASE II-II STDY W/TNM IN PAT.W/ RECURRENT &METAST.BRST CANC				
1 Jun-08-87		AMENDMENT	87-12	DJF		870775
		INV/COMP USE				
		(a) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-000 INV LIST RECD DRUG FROM FEB-MAY '87 (#s 155 THRU 177) BOYLE, EAMONN CA-SOLID; COMPASSIONATE				
		ALLEN EL CA-SOLID; COMPASSIONATE				
		BAGWELL, JOHN CA-SOLID; COMPASSIONATE				
		BROWNE, KENNEDY CA-SOLID; COMPASSIONATE				
		CIMO, PHILIP CA-SOLID; COMPASSIONATE				
		FANGMAN, MICHAEL CA-SOLID; COMPASSIONATE				
		FISHER, JJ CA-SOLID; COMPASSIONATE				
		FORSCHER, CHARLES CA-SOLID; COMPASSIONATE				
		GUY, JERRY T CA-SOLID; COMPASSIONATE				
		HALPERIN, JOSEPH CA-SOLID; COMPASSIONATE				

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
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Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

HAYWARD, M
CA-SOLID; COMPASSIONATE

HURTUBISE, MICHEL
CA-SOLID; COMPASSIONATE

JENKINS, JAY
CA-SOLID; COMPASSIONATE

KAYE, STEPHEN
CA-SOLID; COMPASSIONATE

MANDEL, EUGENE
CA-SOLID; COMPASSIONATE

MARILLEY, RALPH
CA-SOLID; COMPASSIONATE

MOYNIHAN, J
CA-SOLID; COMPASSIONATE

PRASTHOFER, EDW
CA-SOLID; COMPASSIONATE

RYAN, THOMAS
CA-SOLID; COMPASSIONATE

SAWKAR, LAXMIDAS
CA-SOLID; COMPASSIONATE

SLOAN, M
CA-SOLID; COMPASSIONATE

STINE, ANTHONY
CA-SOLID; COMPASSIONATE

I Jun-30-87 ANNUAL REPORT 87-16 DJF 870962

(a) PROGRESS RPT
86 INV.TREATED 3-76 & 89 TREATED 3-77 SINCE LST
RPT.5/31/86

I Jul-29-87 CORRESPONDENCE 87-15 DJF 870963
FDA AUTH X-REF FOR MARKMAN TO STDY INTRAPERITONEAL

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact -----	Resp Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315	ANTICANCER AGENT			
L Aug-03-87		CORRESPONDENCE DR. JD BITRAN CROSS REF OUR IND/REFRAC METATAST BREAST CA	87-19	DJF		871010
L Aug-05-87		AMENDMENT INV / COMP USE	87-20	DJF		871011
		(a) INVESTGTR DOCUMENTN at LEDERLE/003-076-0 INV LIST/COMP USE/JUNE & JULY/#'S 178-185 BOBROW, SAMUEL CA-SOLID; COMPASSIONATE EISENBERG, PETER D CA-SOLID; COMPASSIONATE GLOWALLA, MICHAEL CA-SOLID; COMPASSIONATE KAMPEL, LEWIS CA-SOLID; COMPASSIONATE SALTZMAN, MARK CA-SOLID; COMPASSIONATE SPITZER, GARY CA-SOLID; COMPASSIONATE TIRUMALI, NAGENDRA CA-SOLID; COMPASSIONATE YAMAMOTO, KENNETH S CA-SOLID; COMPASSIONATE				
L Aug-07-87		AMENDMENT PROT AMENDMENT #1 / #3-82	87-21	DJF		871004
		(a) PROTOCOL AMENDMENT /003-082-0 PROT #3-82 AMEND OUTLINES DOSE ESCALATION FOR NEW PATIENTS				
L Aug-12-87		AMENDMENT PI-M.MARKMAN TREATING 2ND PT/OVARIAN CA/1ST PT 5/29/87	87-22	DJF		871009